

EXHIBIT 20

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION REPORT

DIGOXIN TABLETS, 0.125 mg
4,800,000 TABLETS

BATCH #'S 6221A AND 6250A

MPR NO. 14504

Revision No. 00

PROTOCOL NO. 14504-01

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Date Prepared: 9/14/96

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Date: 9/16/96

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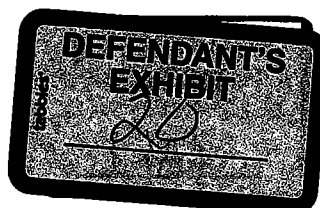
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VP Operations

Date: 9-13-96



AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION SUMMARY

PRODUCT	DIGOXIN TABLETS, 0.125 mg	BATCH	6221A
		BATCH	6250A

The following comments apply to the two 4,800,000 tablet validation batches produced so far in this series.

This report includes data through Compression, which is the finished dosage form.

The process used to produce these batches follows exactly that shown in the normal batch record. Copies of the actual batch records are available in the file.

The data supporting the validation of the analytical methods used may be found in the Analytical Method Validation Report issued for this product.

A copy of the protocol to be followed for this project is included.

Evaluation of the data includes calculation of the Process Capability Index, Cp, when appropriate. Cp is a measure of the ability of a process to produce material that is all within the specification range. It verifies that the entire distribution curve for the data collected falls within the allowable limits. The following equation is used.

$$C_p = \frac{(\text{Upper Limit} - \text{Lower Limit})}{6 \times \text{St. Dev.}}$$

Any value equal to or greater than 1 is acceptable.

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg PROTOCOL NO. 14504 - 01

CONCLUSIONS AND OBSERVATIONS

All samples met the established acceptance criteria.

The process used for this batch size is comparable to that for the 1,600,000 tablet batch size which was previously validated. This process involves combining three blends identical to that of the smaller batch size except for the presence of lubricants. The lubricants are added during preparation of the final blend. Therefore the previous validation is transferable to this process and batches may be shipped as produced.

Based on these batches, the process is considered acceptable for use.

A copy of the previous validation's summary page is included to aid in comparison.

The data verifies the initial acceptance criteria for all parameters. At this point no revision to any of these ranges will be made.

The final blends showed adequate uniformity for all positions sampled, and are comparable to the previous validation.

The data for the compressed tablets passed all testing, with the results centering around the midpoint of the specification ranges and being comparable to the smaller batch size.

Content uniformity results are all within the acceptance criteria, and are essentially comparable to the previous batch size as well as the blend results.

Results for both the final blends and content uniformity center around the label amount.

All Dissolution samples met the USP requirements. The values are comparable to the smaller batch size.

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg PROTOCOL NO. 14504 - 01

The data for each protocol step follows a summary of that step, in the order in which it appears in the protocol.

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg PROTOCOL NO. 14504 - 01

PROTOCOL STEP - TEMPERATURE/HUMIDITY READINGS

Temperature and humidity readings will be taken in the production area. Batch 6221A ran in production between 8/1/96 and 8/9/96 and Batch 6250A ran in production between 8/27/96 - 9/7/96.

RESULTS - See attached data summary sheets.

CONCLUSIONS AND COMMENTS

The temperature ranged from 70 - 77° F, and the relative humidity from 47 - 75%. Data indicates that this product can be made under ambient plant conditions, however it should be noted that the production area is now air conditioned.

AMIDE PHARMACEUTICAL, INC.

TEMPERATURE/HUMIDITY READINGS

PERIOD COVERING DIGOXIN TABLETS, 0.125 mg

BATCH # 6221A

LOCATION	DATE	TEMP. (Deg. F)	RH (%)
Spec. Prod. Gran.	01-Aug-96	77	74
Spec. Prod. Gran.	02-Aug-96	76	75
Spec. Prod. Gran.	07-Aug-96	75	73
Spec. Prod. Gran.	08-Aug-96	76	74
Spec. Prod. Comp.	03-Aug-96	75	66
Spec. Prod. Comp.	05-Aug-96	73	57
Spec. Prod. Comp.	06-Aug-96	72	58
Spec. Prod. Comp.	07-Aug-96	71	57
Spec. Prod. Comp.	08-Aug-96	70	52
Spec. Prod. Comp.	09-Aug-96	71	56

AMIDE PHARMACEUTICAL, INC.

TEMPERATURE/HUMIDITY READINGS

PERIOD COVERING DIGOXIN TABLETS, 0.125mg

BATCH # 6250A

LOCATION	DATE	TEMP. (Deg. F)	RH (%)
Spec. Prod. Gran.	27-Aug-96	72	63
Spec. Prod. Gran.	28-Aug-96	75	68
Spec. Prod. Gran.	03-Sep-96	76	50
Spec. Prod. Comp.	27-Aug-96	72	53
Spec. Prod. Comp.	28-Aug-96	70	47
Spec. Prod. Comp.	29-Aug-96	71	48
Spec. Prod. Comp.	03-Sep-96	73	57
Spec. Prod. Comp.	04-Sep-96	72	49
Spec. Prod. Comp.	05-Sep-96	73	48
Spec. Prod. Comp.	06-Sep-96	73	53
Spec. Prod. Comp.	07-Sep-96	72	64

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg PROTOCOL NO. 14504 - 01

PROTOCOL STEP - BLEND UNIFORMITY

Utilizing a sampling thief, sample each of the blenders from the positions shown on the attached data summary. Separately analyze, and report, each one for active ingredient content.

ACCEPTANCE CRITERIA

Pre-Blend - 85.0 - 115.0 % Th. (Individual)
Final Blend - 85.0 - 115.0 % Th. (Individual)

RESULTS - See the attached data summary.

CONCLUSIONS AND COMMENTS

The three pre-blends for the two batches met all acceptance criteria and showed good uniformity for all positions sampled.

The final blends for these batches met all acceptance criteria and appear to be uniformly blended. They are comparable to the smaller batch size.

The bulk and tamped density results for these batches are comparable to the previous batch size. See the table below to aid in comparison.

	1,600,000 Tablet Batch Size
Density (g/ml)	
Bulk	0.61 - 0.62
Tap	0.89 - 0.91

	Particle Size (% Retained)
US 325	53.0 - 54.5%
US 200	34.1 - 34.8%
US 100	14.6 - 15.3%
US 60	4.1 - 4.7%
US 40	Nil

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

PRE - BLEND - Assay (% Label)

Batch #	6221A	6221A	6221A	6250A	6250A	6250A
Part #	1	2	3	1	2	3
Left Column - Top Left	97.5	102.6	101.1	101.1	102.7	104.2
Left Column - Top Center	99.5	100.3	97.6	101.9	102.6	103.5
Left Column - Top Right	101.9	101.3	102.1	99.3	104.0	104.3
Right Column - Top Left	102.6	100.9	104.0	101.9	102.3	101.9
Right Column - Top Center	102.0	100.5	98.5	100.6	102.5	104.3
Right Column - Top Right	102.5	102.6	102.8	102.4	103.4	102.9
Middle Left	99.0	104.6	104.1	100.1	103.3	103.8
Middle Center	101.1	102.6	105.8	103.6	103.3	103.7
Middle Right	101.2	99.8	103.0	103.4	101.8	104.1
Bottom Left	102.0	100.1	102.0	102.9	102.8	102.2
Bottom Right	102.4	102.5	102.0	101.9	101.2	102.0
Average	101.1	101.6	102.1	101.7	102.7	103.4
St Dev.	1.7	1.5	2.4	1.4	0.8	0.9
RSD	1.7	1.5	2.3	1.3	0.8	0.9

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg****FINAL BLEND - ASSAY (% Label)**

Batch #	6221A	6250A
Center - Top	97.7	105.0
Center - Middle	98.3	105.2
Center - Bottom	100.5	102.3
Left - Slope	101.1	99.5
Right - Slope	99.2	101.2
Left - Middle	94.9	96.8
Left - Top	100.3	99.1
Right - Middle	100.8	98.9
Right - Top	99.4	97.9
Front - Middle	101.1	96.0
Front - Top	100.9	93.3
Rear - Middle	101.8	99.2
Rear - Top	101.0	96.9
Average	99.8	99.3
St Dev.	1.9	3.4
RSD	1.9	3.5

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION*****DIGOXIN TABLETS, 0.125 mg***

FINAL BLEND - Density/Particle Size - Batch # 6221A

Density (g/ml)

Sample	Top	Middle	Bottom
Bulk	0.61	0.61	0.62
Tap	0.87	0.84	0.86

Particle Size (% Retained)

Mesh Size	Top	Middle	Bottom
325	50.1	49.3	49.3
200	29.4	28.8	29.1
100	13.0	13.8	13.7
60	3.7	3.5	3.9
40	Nil	Nil	Nil

FINAL BLEND - Density/Particle Size - Batch # 6250A

Density (g/ml)

Sample	Top	Middle	Bottom
Bulk	0.63	0.63	0.63
Tap	0.88	0.85	0.85

Particle Size (% Retained)

Mesh Size	Top	Middle	Bottom
325	53.1	54.5	54.0
200	29.8	30.8	30.9
100	12.4	12.6	12.8
60	2.8	2.6	2.4
40	Nil	Nil	Nil

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg PROTOCOL NO. 14504 - 01

PROTOCOL STEP - COMPRESSION

Samples were taken from each side of the press each hour and were evaluated for the following parameters.

Weight (n = 10)
Thickness (n = 5)
Hardness (n = 5)

These samples will be arranged chronologically and the batch divided into thirds. Front and rear will be analyzed separately as follows.

Friability 10 g - 1 run

Content uniformity is to be run across the entire batch. One tablet from each sample taken is to be run from the front, and one from the rear. A minimum of 30 is required from each side.

Dissolution testing will consist of 12 tablets taken from both composites of the front and rear with as even a distribution as possible.

ACCEPTANCE CRITERIA

Weight: 0.097 - 0.113 g
Hardness: 1.0 - 6.0 KP
Thickness: 2.0 - 3.0 mm
Friability: NMT 1.0 %
Dissolution: Meets USP Requirement
Disintegration: N/A (for characterization only)
Content Uniformity: 85.0 - 115.0 % TH, (RSD NMT 6.0 %)
Assay: 90.0 - 105.0 % Label

RESULTS - See attached data summary sheets.

AMIDE PHARMACEUTICAL, INC.
PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg PROTOCOL NO. 14504 - 01

CONCLUSIONS AND COMMENTS

The samples met all acceptance criteria.

The values for weight, hardness, and thickness for these batches were comparable to the smaller batch size and showed no unusual shifts or trends. The overall averages for weight, hardness and thickness are very close to the midpoints of the preset ranges. Therefore, no revisions to these limits are indicated by the validation data.

Content Uniformity was within limits for all samples tested, with no significant trends being observed. All values were within 98 - 105 % L. The values obtained were observed to agree favorably with the blend assays and the previous validation. It should be noted that the averages for the blend assays, and the content uniformity results are essentially the label amount.

All Dissolution samples for this batch met the USP requirements. This statement is true for both USP XXII (60 Min.) and XXIII (15 & 60 Min.). The values for this batch was comparable to the smaller batch size.

Friability values were all well within the acceptance criteria, and comparable to the previous batch size.

The results for the overall composites are attached. These are also all within the acceptance criteria, and are essentially comparable to those obtained for the smaller batch size.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 6221A

Compression - Weight (g) - Front

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
8/3/96	12:50 PM	0.108	0.104	0.100	0.104	0.103	0.103	0.104	0.103	0.104	0.105	0.104	0.002	1.9
8/3/96	1:55 PM	0.107	0.104	0.106	0.102	0.105	0.106	0.104	0.106	0.105	0.103	0.105	0.002	1.5
8/3/96	2:45 PM	0.106	0.105	0.105	0.106	0.106	0.106	0.105	0.107	0.107	0.105	0.106	0.001	0.7
8/5/96	7:50 AM	0.106	0.104	0.108	0.105	0.106	0.105	0.105	0.104	0.106	0.105	0.105	0.001	1.1
8/5/96	8:45 AM	0.107	0.106	0.105	0.107	0.107	0.103	0.106	0.105	0.105	0.106	0.106	0.001	1.2
8/5/96	9:30 AM	0.107	0.104	0.104	0.103	0.103	0.105	0.104	0.104	0.107	0.105	0.105	0.001	1.4
8/5/96	10:20 AM	0.105	0.105	0.107	0.104	0.106	0.106	0.105	0.106	0.105	0.104	0.105	0.001	0.9
8/5/96	11:15 AM	0.107	0.106	0.103	0.107	0.105	0.105	0.104	0.106	0.105	0.103	0.105	0.001	1.4
8/5/96	12:20 PM	0.104	0.103	0.104	0.103	0.106	0.105	0.104	0.104	0.106	0.105	0.104	0.001	1.0
8/5/96	1:50 PM	0.105	0.106	0.106	0.104	0.104	0.105	0.107	0.103	0.105	0.105	0.105	0.001	1.1
8/5/96	3:45 PM	0.105	0.106	0.107	0.102	0.104	0.106	0.106	0.105	0.106	0.105	0.105	0.002	1.5
8/5/96	4:50 PM	0.105	0.103	0.105	0.108	0.103	0.103	0.105	0.105	0.105	0.104	0.105	0.002	1.4
8/5/96	5:50 PM	0.106	0.107	0.106	0.105	0.104	0.104	0.107	0.104	0.103	0.105	0.105	0.001	1.3
8/6/96	7:45 AM	0.105	0.104	0.106	0.103	0.102	0.105	0.108	0.104	0.105	0.105	0.105	0.002	1.6
8/6/96	8:45 AM	0.104	0.105	0.103	0.104	0.103	0.104	0.103	0.105	0.102	0.106	0.104	0.001	1.2
8/6/96	9:40 AM	0.105	0.106	0.106	0.107	0.104	0.105	0.105	0.106	0.105	0.104	0.105	0.001	1.1
8/6/96	10:55 AM	0.103	0.104	0.106	0.108	0.104	0.104	0.106	0.104	0.105	0.103	0.105	0.002	1.9
8/6/96	11:55 AM	0.105	0.102	0.107	0.108	0.105	0.105	0.104	0.108	0.103	0.105	0.105	0.001	0.9
8/6/96	12:50 PM	0.105	0.105	0.106	0.106	0.104	0.106	0.105	0.105	0.105	0.103	0.105	0.001	1.2
8/6/96	1:50 PM	0.103	0.106	0.103	0.104	0.104	0.104	0.103	0.103	0.108	0.108	0.106	0.002	1.5
8/6/96	2:50 PM	0.106	0.106	0.107	0.106	0.107	0.106	0.110	0.101	0.106	0.105	0.105	0.002	2.3
8/6/96	3:40 PM	0.107	0.104	0.105	0.105	0.103	0.106	0.107	0.106	0.105	0.104	0.106	0.001	1.3
8/6/96	4:40 PM	0.107	0.105	0.107	0.106	0.107	0.108	0.104	0.105	0.106	0.104	0.105	0.002	1.6
8/6/96	5:40 PM	0.107	0.106	0.103	0.106	0.104	0.108	0.104	0.105	0.103	0.104	0.105	0.002	1.6
8/7/96	7:45 AM	0.107	0.105	0.106	0.104	0.103	0.104	0.104	0.107	0.103	0.107	0.105	0.002	1.6
8/7/96	8:30 AM	0.106	0.104	0.104	0.105	0.107	0.106	0.104	0.106	0.106	0.105	0.105	0.001	1.0
8/7/96	9:40 AM	0.105	0.104	0.105	0.107	0.103	0.105	0.106	0.108	0.103	0.104	0.105	0.002	1.6
8/7/96	10:50 AM	0.105	0.106	0.106	0.104	0.105	0.105	0.108	0.103	0.104	0.105	0.105	0.001	1.3
8/7/96	11:50 AM	0.108	0.106	0.106	0.103	0.107	0.107	0.107	0.104	0.105	0.105	0.106	0.002	1.4
8/7/96	12:50 PM	0.104	0.105	0.105	0.106	0.105	0.105	0.104	0.104	0.105	0.103	0.105	0.001	0.8
8/7/96	1:50 PM	0.103	0.104	0.104	0.106	0.104	0.102	0.104	0.103	0.104	0.106	0.104	0.001	1.0
8/7/96	2:50 PM	0.106	0.107	0.106	0.107	0.107	0.105	0.106	0.107	0.105	0.105	0.105	0.001	0.8
8/7/96	3:45 PM	0.106	0.105	0.106	0.104	0.105	0.106	0.106	0.105	0.104	0.105	0.105	0.001	0.7
8/8/96	7:45 AM	0.107	0.104	0.105	0.105	0.105	0.103	0.105	0.105	0.105	0.104	0.105	0.001	0.8
8/8/96	8:35 AM	0.105	0.103	0.105	0.106	0.103	0.103	0.102	0.104	0.104	0.104	0.104	0.001	1.2
8/8/96	9:25 AM	0.105	0.106	0.105	0.103	0.103	0.106	0.106	0.105	0.105	0.104	0.105	0.001	0.9
8/8/96	10:55 AM	0.105	0.105	0.106	0.105	0.105	0.104	0.103	0.105	0.105	0.105	0.104	0.001	0.9
8/8/96	11:50 AM	0.105	0.105	0.106	0.105	0.106	0.105	0.104	0.105	0.106	0.105	0.105	0.001	1.0
8/8/96	12:50 PM	0.107	0.103	0.105	0.106	0.105	0.104	0.105	0.106	0.104	0.105	0.105	0.001	1.2
8/8/96	2:00 PM	0.105	0.105	0.106	0.106	0.108	0.107	0.105	0.105	0.105	0.105	0.105	0.001	1.0
8/8/96	2:50 PM	0.104	0.104	0.106	0.107	0.102	0.104	0.105	0.107	0.105	0.105	0.105	0.002	1.3
8/8/96	3:50 PM	0.103	0.105	0.106	0.105	0.106	0.105	0.106	0.106	0.106	0.105	0.107	0.001	1.0
8/8/96	4:40 PM	0.107	0.105	0.106	0.105	0.108	0.104	0.106	0.104	0.104	0.106	0.106	0.001	1.3
8/8/96	5:35 PM	0.103	0.107	0.104	0.106	0.104	0.106	0.105	0.107	0.105	0.103	0.105	0.001	1.4
8/8/96	7:40 AM	0.108	0.106	0.107	0.106	0.106	0.105	0.107	0.106	0.106	0.106	0.106	0.001	1.0
8/8/96	8:35 AM	0.107	0.105	0.107	0.103	0.105	0.105	0.106	0.104	0.107	0.108	0.106	0.002	1.5
8/8/96	9:35 AM	0.103	0.104	0.107	0.106	0.106	0.104	0.105	0.105	0.105	0.107	0.105	0.001	1.3
8/9/96	10:45 AM	0.105	0.105	0.107	0.103	0.106	0.106	0.106	0.104	0.105	0.105	0.105	0.001	1.4
8/9/96	11:40 AM	0.108	0.105	0.105	0.104	0.105	0.106	0.105	0.104	0.106	0.107	0.106	0.001	1.3
8/9/96	12:30 PM	0.103	0.107	0.105	0.104	0.106	0.105	0.106	0.108	0.107	0.106	0.106	0.001	1.4
8/9/96	1:45 PM	0.107	0.105	0.106	0.103	0.104	0.105	0.108	0.105	0.100	0.105	0.105	0.002	2.1

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 6221A

Compression - Weight (g) - Rear

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St.Dev.	RSD
8/3/96	12:50 PM	0.104	0.107	0.104	0.105	0.108	0.106	0.107	0.104	0.105	0.106	0.106	0.001	1.4
8/3/96	1:55 PM	0.104	0.105	0.103	0.104	0.103	0.105	0.104	0.104	0.106	0.105	0.104	0.001	0.9
8/3/96	2:45 PM	0.107	0.107	0.106	0.103	0.107	0.105	0.106	0.104	0.105	0.106	0.106	0.001	1.3
8/5/96	7:50 AM	0.104	0.105	0.105	0.105	0.107	0.105	0.104	0.104	0.103	0.108	0.105	0.001	1.4
8/5/96	8:45 AM	0.105	0.103	0.105	0.108	0.107	0.107	0.105	0.104	0.105	0.106	0.106	0.002	1.4
8/5/96	9:30 AM	0.107	0.104	0.107	0.105	0.106	0.104	0.106	0.107	0.107	0.105	0.106	0.001	1.2
8/5/96	10:20 AM	0.105	0.106	0.107	0.108	0.104	0.106	0.107	0.106	0.105	0.104	0.106	0.001	1.2
8/5/96	11:15 AM	0.103	0.103	0.107	0.105	0.106	0.102	0.106	0.107	0.108	0.105	0.106	0.002	1.6
8/5/96	12:20 PM	0.103	0.104	0.105	0.106	0.104	0.105	0.105	0.105	0.103	0.103	0.104	0.002	1.6
8/5/96	1:50 PM	0.108	0.104	0.107	0.106	0.107	0.105	0.105	0.105	0.103	0.104	0.105	0.002	1.7
8/5/96	3:45 PM	0.107	0.105	0.105	0.104	0.105	0.105	0.107	0.106	0.104	0.105	0.105	0.001	1.0
8/5/96	4:50 PM	0.105	0.103	0.105	0.104	0.104	0.107	0.105	0.105	0.106	0.105	0.105	0.001	1.0
8/5/96	5:50 PM	0.107	0.105	0.106	0.104	0.105	0.106	0.104	0.105	0.106	0.108	0.106	0.001	1.2
8/6/96	7:45 AM	0.106	0.103	0.108	0.105	0.106	0.104	0.108	0.102	0.103	0.103	0.105	0.002	2.1
8/6/96	8:45 AM	0.105	0.104	0.103	0.105	0.103	0.105	0.103	0.105	0.103	0.104	0.104	0.001	0.9
8/6/96	9:40 AM	0.108	0.104	0.109	0.103	0.104	0.104	0.105	0.104	0.104	0.105	0.105	0.002	1.9
8/6/96	10:55 AM	0.105	0.104	0.104	0.104	0.104	0.106	0.106	0.107	0.103	0.104	0.105	0.001	1.3
8/6/96	11:55 AM	0.105	0.104	0.106	0.105	0.104	0.104	0.104	0.104	0.105	0.105	0.105	0.001	0.7
8/6/96	12:50 PM	0.106	0.105	0.105	0.104	0.105	0.104	0.104	0.104	0.105	0.105	0.105	0.001	0.6
8/6/96	1:50 PM	0.105	0.104	0.105	0.105	0.104	0.105	0.104	0.104	0.106	0.104	0.105	0.001	0.7
8/6/96	2:50 PM	0.102	0.105	0.105	0.103	0.104	0.106	0.105	0.108	0.106	0.108	0.105	0.002	1.8
8/6/96	3:40 PM	0.103	0.105	0.106	0.105	0.106	0.104	0.103	0.104	0.104	0.106	0.105	0.001	1.1
8/6/96	4:40 PM	0.105	0.106	0.104	0.103	0.105	0.106	0.105	0.106	0.105	0.104	0.105	0.001	0.9
8/6/96	5:40 PM	0.105	0.104	0.104	0.106	0.105	0.105	0.104	0.105	0.103	0.105	0.105	0.001	0.8
8/7/96	7:45 AM	0.105	0.104	0.106	0.107	0.105	0.106	0.103	0.104	0.104	0.106	0.105	0.001	1.2
8/7/96	8:30 AM	0.103	0.105	0.104	0.106	0.105	0.102	0.106	0.103	0.103	0.102	0.104	0.002	1.5
8/7/96	9:40 AM	0.105	0.105	0.107	0.104	0.104	0.107	0.106	0.106	0.107	0.105	0.106	0.001	1.1
8/7/96	10:50 AM	0.105	0.107	0.103	0.106	0.107	0.106	0.106	0.106	0.107	0.105	0.106	0.001	1.1
8/7/96	11:50 AM	0.106	0.104	0.104	0.103	0.105	0.105	0.104	0.107	0.104	0.107	0.105	0.001	1.3
8/7/96	12:50 PM	0.107	0.108	0.107	0.107	0.105	0.108	0.104	0.105	0.105	0.107	0.106	0.001	1.3
8/7/96	1:50 PM	0.104	0.103	0.103	0.104	0.104	0.104	0.105	0.104	0.102	0.103	0.104	0.001	0.8
8/7/96	2:50 PM	0.106	0.105	0.106	0.105	0.104	0.105	0.104	0.107	0.104	0.105	0.105	0.001	0.9
8/7/96	3:45 PM	0.108	0.104	0.105	0.104	0.106	0.104	0.104	0.105	0.103	0.104	0.105	0.001	1.4
8/8/96	7:45 AM	0.106	0.107	0.108	0.107	0.107	0.106	0.106	0.107	0.106	0.105	0.107	0.001	0.8
8/8/96	8:35 AM	0.106	0.107	0.108	0.105	0.108	0.107	0.106	0.105	0.105	0.104	0.106	0.001	1.3
8/8/96	9:25 AM	0.104	0.105	0.105	0.104	0.105	0.106	0.102	0.106	0.106	0.106	0.105	0.001	1.2
8/8/96	10:55 AM	0.105	0.104	0.103	0.103	0.105	0.103	0.102	0.105	0.103	0.103	0.104	0.001	1.0
8/8/96	11:50 AM	0.106	0.107	0.105	0.104	0.103	0.105	0.106	0.104	0.104	0.104	0.105	0.001	1.2
8/8/96	12:50 PM	0.103	0.106	0.104	0.105	0.105	0.102	0.104	0.103	0.103	0.102	0.104	0.001	1.3
8/8/96	2:00 PM	0.106	0.106	0.105	0.106	0.108	0.104	0.105	0.104	0.105	0.105	0.105	0.001	1.1
8/8/96	2:50 PM	0.105	0.103	0.103	0.103	0.105	0.104	0.102	0.104	0.105	0.103	0.104	0.001	1.0
8/8/96	3:50 PM	0.105	0.105	0.106	0.106	0.105	0.104	0.104	0.106	0.105	0.106	0.105	0.001	0.7
8/8/96	4:40 PM	0.104	0.106	0.105	0.104	0.106	0.105	0.104	0.105	0.105	0.107	0.105	0.001	0.9
8/8/96	5:35 PM	0.105	0.104	0.105	0.105	0.104	0.103	0.107	0.105	0.107	0.105	0.105	0.001	1.2
8/9/96	7:40 AM	0.106	0.103	0.104	0.104	0.105	0.106	0.105	0.104	0.106	0.104	0.105	0.001	1.0
8/9/96	8:35 AM	0.106	0.105	0.105	0.104	0.106	0.106	0.105	0.104	0.103	0.103	0.105	0.001	1.1
8/9/96	9:35 AM	0.104	0.102	0.102	0.107	0.106	0.107	0.105	0.107	0.107	0.104	0.105	0.002	1.9
8/9/96	10:45 AM	0.104	0.106	0.107	0.103	0.106	0.104	0.107	0.107	0.104	0.105	0.105	0.001	1.4
8/9/96	11:40 AM	0.104	0.107	0.103	0.106	0.105	0.106	0.105	0.102	0.103	0.106	0.105	0.002	1.6
8/9/96	12:30 PM	0.107	0.106	0.105	0.102	0.105	0.102	0.104	0.105	0.103	0.102	0.104	0.002	1.7
8/9/96	1:45 PM	0.105	0.105	0.105	0.105	0.104	0.106	0.106	0.108	0.107	0.105	0.106	0.001	1.1

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch #: 6250A

Compression - Weight (mg) - Front

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
8/29/96	2:25 PM	0.109	0.107	0.108	0.107	0.108	0.105	0.107	0.108	0.107	0.108	0.107	0.001	1.0
8/29/96	3:25 PM	0.107	0.106	0.105	0.105	0.106	0.106	0.105	0.105	0.107	0.106	0.106	0.001	0.7
9/3/96	7:45 AM	0.105	0.106	0.105	0.106	0.109	0.104	0.107	0.106	0.107	0.107	0.106	0.001	1.3
9/3/96	9:00 AM	0.106	0.107	0.107	0.107	0.104	0.108	0.107	0.105	0.106	0.110	0.107	0.002	1.5
9/3/96	10:00 AM	0.108	0.106	0.107	0.106	0.107	0.105	0.107	0.106	0.110	0.108	0.107	0.001	1.3
9/3/96	11:00 AM	0.109	0.109	0.108	0.109	0.111	0.108	0.107	0.110	0.109	0.109	0.109	0.001	1.0
9/3/96	12:10 PM	0.107	0.107	0.106	0.107	0.107	0.108	0.108	0.108	0.106	0.107	0.107	0.001	0.7
9/3/96	1:10 PM	0.106	0.108	0.105	0.107	0.105	0.108	0.108	0.108	0.108	0.109	0.107	0.001	1.3
9/4/96	2:25 PM	0.106	0.108	0.106	0.107	0.104	0.108	0.105	0.107	0.107	0.107	0.107	0.001	1.2
9/4/96	3:30 PM	0.109	0.108	0.107	0.107	0.108	0.108	0.108	0.108	0.109	0.109	0.108	0.001	0.7
9/4/96	4:10 PM	0.105	0.106	0.106	0.105	0.105	0.104	0.105	0.106	0.107	0.108	0.106	0.001	1.1
9/4/96	5:10 PM	0.105	0.104	0.105	0.106	0.104	0.106	0.105	0.105	0.105	0.105	0.105	0.001	0.6
9/4/96	7:55 AM	0.107	0.105	0.108	0.107	0.107	0.108	0.105	0.104	0.107	0.107	0.107	0.001	1.3
9/4/96	8:55 AM	0.107	0.105	0.106	0.105	0.107	0.107	0.107	0.108	0.106	0.106	0.106	0.001	1.2
9/4/96	9:55 AM	0.107	0.104	0.105	0.107	0.107	0.107	0.104	0.106	0.107	0.106	0.106	0.001	1.2
9/4/96	11:10 AM	0.103	0.104	0.104	0.104	0.108	0.106	0.105	0.107	0.107	0.105	0.105	0.001	1.4
9/4/96	12:10 PM	0.104	0.105	0.107	0.104	0.106	0.106	0.106	0.104	0.104	0.104	0.104	0.001	1.4
9/4/96	1:00 PM	0.106	0.104	0.108	0.103	0.105	0.104	0.106	0.104	0.104	0.104	0.104	0.001	1.4
9/4/96	2:30 PM	0.105	0.105	0.106	0.104	0.107	0.108	0.103	0.105	0.104	0.108	0.106	0.002	1.6
9/4/96	3:30 PM	0.106	0.105	0.104	0.105	0.105	0.108	0.104	0.105	0.106	0.105	0.105	0.001	1.1
9/5/96	8:00 AM	0.107	0.106	0.106	0.107	0.107	0.108	0.107	0.104	0.106	0.105	0.106	0.001	0.9
9/5/96	9:00 AM	0.105	0.105	0.107	0.105	0.105	0.105	0.105	0.103	0.106	0.105	0.105	0.001	0.9
9/5/96	10:00 AM	0.106	0.108	0.103	0.104	0.107	0.104	0.106	0.103	0.102	0.106	0.105	0.002	1.9
9/5/96	10:55 AM	0.104	0.105	0.106	0.107	0.104	0.107	0.105	0.104	0.107	0.103	0.105	0.001	1.4
9/5/96	12:05 PM	0.106	0.104	0.106	0.108	0.106	0.107	0.107	0.106	0.104	0.105	0.106	0.001	1.2
9/5/96	1:00 PM	0.104	0.103	0.103	0.103	0.105	0.104	0.105	0.103	0.103	0.104	0.104	0.001	0.8
9/5/96	2:10 PM	0.105	0.105	0.106	0.104	0.105	0.105	0.102	0.104	0.103	0.102	0.104	0.001	1.3
9/5/96	3:00 PM	0.105	0.102	0.108	0.105	0.108	0.104	0.105	0.104	0.105	0.102	0.105	0.002	1.7
9/5/96	3:50 PM	0.105	0.107	0.106	0.104	0.105	0.107	0.105	0.104	0.103	0.105	0.105	0.001	1.2
9/5/96	4:50 PM	0.104	0.104	0.102	0.107	0.104	0.107	0.102	0.105	0.110	0.101	0.105	0.003	2.7
9/5/96	5:50 PM	0.104	0.104	0.102	0.105	0.105	0.104	0.105	0.105	0.103	0.104	0.104	0.001	1.0
9/6/96	8:00 AM	0.105	0.103	0.106	0.105	0.106	0.104	0.105	0.106	0.102	0.102	0.104	0.001	1.2
9/6/96	9:10 AM	0.103	0.104	0.104	0.104	0.105	0.104	0.105	0.103	0.104	0.104	0.104	0.001	1.0
9/6/96	10:10 AM	0.104	0.105	0.105	0.105	0.106	0.105	0.105	0.106	0.102	0.102	0.104	0.001	0.8
9/6/96	11:30 AM	0.103	0.103	0.103	0.102	0.104	0.102	0.104	0.107	0.103	0.104	0.104	0.001	1.6
9/6/96	12:20 PM	0.103	0.105	0.105	0.103	0.105	0.104	0.105	0.103	0.105	0.105	0.105	0.001	1.1
9/6/96	1:20 PM	0.103	0.104	0.104	0.105	0.107	0.105	0.104	0.103	0.104	0.106	0.104	0.001	1.0
9/6/96	2:25 PM	0.102	0.103	0.104	0.107	0.106	0.105	0.102	0.105	0.105	0.104	0.104	0.001	1.2
9/6/96	3:30 PM	0.105	0.105	0.104	0.107	0.106	0.107	0.107	0.106	0.105	0.107	0.106	0.001	0.7
9/7/96	7:25 AM	0.106	0.107	0.105	0.108	0.107	0.106	0.107	0.106	0.105	0.103	0.106	0.001	1.4
9/7/96	8:30 AM	0.105	0.104	0.103	0.106	0.105	0.106	0.102	0.105	0.102	0.104	0.104	0.001	1.1
9/7/96	9:30 AM	0.104	0.103	0.105	0.105	0.105	0.106	0.106	0.105	0.102	0.104	0.105	0.001	1.1
9/7/96	10:30 AM	0.104	0.103	0.104	0.104	0.105	0.104	0.103	0.104	0.103	0.105	0.104	0.001	0.7

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch #: 6250A

Compression - Weight (mg) - Rear

Date	Time	1	2	3	4	5	6	7	8	9	10	Average	St Dev.	RSD
8/29/96	2:25 PM	0.102	0.103	0.104	0.103	0.098	0.103	0.104	0.102	0.108	0.104	0.103	0.002	2.4
8/29/96	3:25 PM	0.106	0.108	0.105	0.103	0.103	0.103	0.106	0.104	0.100	0.107	0.105	0.002	2.3
9/3/96	7:45 AM	0.104	0.103	0.104	0.101	0.100	0.107	0.102	0.103	0.100	0.102	0.103	0.002	2.1
9/3/96	9:00 AM	0.100	0.103	0.105	0.104	0.104	0.103	0.104	0.101	0.099	0.100	0.102	0.002	2.1
9/3/96	10:00 AM	0.103	0.105	0.101	0.097	0.102	0.104	0.106	0.100	0.101	0.104	0.102	0.003	2.6
9/3/96	11:00 AM	0.109	0.101	0.104	0.106	0.103	0.106	0.106	0.106	0.100	0.102	0.104	0.003	2.7
9/3/96	12:10 PM	0.109	0.105	0.103	0.101	0.108	0.108	0.106	0.103	0.104	0.106	0.105	0.003	2.5
9/3/96	1:10 PM	0.109	0.103	0.104	0.107	0.105	0.108	0.105	0.102	0.105	0.104	0.105	0.002	1.9
9/4/96	2:25 PM	0.102	0.104	0.101	0.108	0.107	0.107	0.103	0.103	0.104	0.104	0.104	0.002	2.2
9/4/96	3:30 PM	0.105	0.106	0.107	0.108	0.105	0.105	0.104	0.107	0.104	0.106	0.106	0.001	1.3
9/4/96	4:10 PM	0.105	0.107	0.104	0.105	0.103	0.105	0.106	0.107	0.105	0.104	0.105	0.001	1.2
9/4/96	5:10 PM	0.106	0.107	0.104	0.102	0.106	0.106	0.106	0.104	0.107	0.105	0.105	0.002	1.5
9/4/96	7:55 AM	0.107	0.104	0.106	0.104	0.105	0.108	0.108	0.109	0.105	0.106	0.106	0.002	1.6
9/4/96	8:55 AM	0.104	0.106	0.105	0.108	0.105	0.105	0.102	0.105	0.107	0.104	0.105	0.002	1.7
9/4/96	9:55 AM	0.104	0.108	0.107	0.105	0.106	0.105	0.106	0.105	0.104	0.105	0.106	0.001	1.2
9/4/96	11:10 AM	0.109	0.105	0.109	0.104	0.103	0.107	0.103	0.104	0.104	0.106	0.105	0.002	2.2
9/4/96	12:10 PM	0.102	0.105	0.105	0.104	0.106	0.103	0.103	0.106	0.105	0.108	0.105	0.002	1.8
9/4/96	1:00 PM	0.105	0.104	0.105	0.108	0.105	0.103	0.105	0.107	0.105	0.106	0.105	0.001	1.0
9/4/96	2:30 PM	0.110	0.104	0.108	0.102	0.106	0.104	0.107	0.104	0.111	0.105	0.106	0.003	2.7
9/4/96	3:30 PM	0.105	0.105	0.102	0.104	0.102	0.104	0.106	0.104	0.104	0.103	0.104	0.001	1.2
9/5/96	8:00 AM	0.105	0.105	0.107	0.106	0.106	0.103	0.108	0.107	0.105	0.107	0.106	0.001	1.1
9/5/96	9:00 AM	0.108	0.105	0.106	0.105	0.106	0.105	0.108	0.106	0.106	0.106	0.105	0.002	1.9
9/5/96	10:00 AM	0.104	0.107	0.104	0.108	0.107	0.104	0.103	0.102	0.106	0.106	0.105	0.003	2.6
9/5/96	10:55 AM	0.106	0.102	0.105	0.104	0.101	0.102	0.105	0.109	0.101	0.109	0.102	0.003	2.8
9/5/96	12:05 PM	0.105	0.103	0.104	0.105	0.098	0.106	0.102	0.101	0.102	0.107	0.102	0.002	2.0
9/5/96	1:00 PM	0.103	0.102	0.099	0.102	0.103	0.102	0.102	0.101	0.102	0.107	0.102	0.002	3.0
9/5/96	2:10 PM	0.109	0.103	0.100	0.102	0.105	0.104	0.100	0.098	0.104	0.104	0.103	0.003	2.2
9/5/96	3:00 PM	0.106	0.105	0.110	0.108	0.103	0.106	0.108	0.107	0.104	0.103	0.106	0.001	1.4
9/5/96	3:50 PM	0.106	0.105	0.107	0.109	0.105	0.106	0.107	0.105	0.104	0.105	0.106	0.002	1.5
9/5/96	4:50 PM	0.103	0.102	0.106	0.102	0.105	0.104	0.104	0.106	0.104	0.101	0.103	0.002	2.3
9/5/96	5:50 pm	0.103	0.103	0.100	0.102	0.101	0.100	0.108	0.104	0.103	0.101	0.103	0.001	0.6
9/6/96	8:00 AM	0.106	0.105	0.106	0.105	0.106	0.105	0.106	0.107	0.105	0.106	0.106	0.001	1.2
9/6/96	9:10 AM	0.103	0.104	0.104	0.104	0.105	0.104	0.105	0.106	0.102	0.102	0.104	0.001	1.1
9/6/96	10:10 AM	0.106	0.104	0.103	0.106	0.104	0.106	0.103	0.105	0.103	0.104	0.104	0.002	1.9
9/6/96	11:30 AM	0.103	0.102	0.104	0.102	0.104	0.101	0.106	0.103	0.102	0.103	0.103	0.001	1.4
9/6/96	12:20 PM	0.103	0.102	0.104	0.102	0.103	0.104	0.105	0.104	0.106	0.107	0.105	0.001	1.2
9/6/96	1:20 PM	0.105	0.104	0.105	0.103	0.103	0.104	0.103	0.104	0.104	0.105	0.103	0.002	1.5
9/6/96	2:25 PM	0.106	0.102	0.103	0.102	0.101	0.102	0.103	0.103	0.104	0.105	0.105	0.001	0.9
9/6/96	3:30 PM	0.104	0.106	0.104	0.106	0.104	0.104	0.106	0.105	0.106	0.105	0.106	0.001	1.0
9/7/96	7:25 AM	0.106	0.105	0.107	0.107	0.108	0.106	0.105	0.105	0.105	0.103	0.105	0.002	1.6
9/7/96	8:30 AM	0.106	0.105	0.105	0.106	0.106	0.104	0.107	0.104	0.102	0.103	0.105	0.002	1.5
9/7/96	9:30 AM	0.106	0.105	0.102	0.105	0.106	0.104	0.104	0.102	0.102	0.105	0.104	0.001	0.9
9/7/96	10:30 AM	0.105	0.103	0.105	0.105	0.104	0.108	0.105	0.106	0.104	0.104	0.105	0.001	0.9

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 6221A

Compression - Hardness (kp) - Front

Date	Time	1	2	3	4	5	Average	St. Dev.	RSD
8/3/96	12:50 PM	3.9	3.8	3.8	4.4	3.0	3.8	0.5	13.3
8/3/96	1:55 PM	4.3	4.5	4.6	4.6	4.2	4.4	0.2	4.1
8/3/96	2:45 PM	4.6	4.6	4.0	4.6	4.6	4.5	0.3	6.0
8/5/96	7:50 AM	3.9	4.3	4.0	4.3	4.3	4.2	0.2	4.7
8/5/96	8:45 AM	4.0	4.2	4.0	4.1	4.5	4.2	0.2	5.0
8/5/96	9:30 AM	3.8	4.2	3.9	3.9	4.4	4.0	0.3	6.2
8/5/96	10:20 AM	4.0	4.1	4.3	4.7	4.3	4.3	0.3	6.3
8/5/96	11:15 AM	4.3	4.5	4.0	4.1	4.2	4.2	0.2	4.6
8/5/96	12:20 PM	3.9	3.7	4.0	4.3	4.1	4.0	0.2	5.6
8/5/96	1:50 PM	3.9	4.4	3.7	3.9	3.8	3.9	0.3	6.9
8/5/96	3:45 PM	3.7	4.0	4.1	3.9	3.9	3.9	0.1	3.8
8/5/96	4:50 PM	4.4	3.7	4.0	3.8	3.8	3.9	0.3	7.1
8/5/96	5:50 PM	3.6	4.1	4.0	4.1	4.3	4.0	0.3	6.4
8/6/96	7:45 AM	3.7	3.5	3.3	3.6	4.1	3.6	0.3	8.1
8/6/96	8:45 AM	3.7	3.4	3.5	3.7	3.5	3.6	0.1	3.8
8/6/96	9:40 AM	3.5	3.6	3.7	4.2	3.8	3.8	0.3	7.2
8/6/96	10:55 AM	4.3	4.2	3.9	4.0	3.6	4.0	0.3	6.8
8/6/96	11:55 AM	3.5	4.1	4.3	3.9	4.8	4.1	0.5	11.7
8/6/96	12:50 PM	5.3	3.6	4.0	3.9	4.3	4.2	0.7	15.5
8/6/96	1:50 PM	3.9	3.3	3.6	4.3	4.4	3.9	0.5	11.9
8/6/96	2:50 PM	4.4	3.6	4.7	4.0	4.2	4.1	0.4	9.8
8/6/96	3:40 PM	4.4	4.2	4.0	4.5	4.0	4.2	0.2	5.4
8/6/96	4:40 PM	3.9	4.2	4.3	4.2	4.2	4.2	0.2	3.6
8/6/96	5:40 PM	3.9	3.7	4.0	4.0	4.2	4.0	0.2	4.6
8/7/96	7:45 AM	3.8	3.7	3.5	3.9	3.7	3.7	0.1	4.0
8/7/96	8:30 AM	4.3	4.0	3.9	3.9	4.4	4.1	0.2	5.7
8/7/96	9:40 AM	3.4	4.1	4.1	4.0	4.0	3.9	0.3	7.5
8/7/96	10:50 AM	3.5	3.5	4.2	4.5	4.4	4.0	0.5	12.1
8/7/96	11:50 AM	3.9	4.0	3.9	4.1	3.8	3.9	0.1	2.9
8/7/96	12:50 PM	3.4	3.7	4.0	3.5	3.9	3.7	0.3	6.9
8/7/96	1:50 PM	3.4	3.7	3.7	4.1	3.9	3.8	0.3	6.9
8/7/96	2:50 PM	4.1	4.1	4.4	4.0	3.9	4.1	0.2	4.6
8/7/96	3:45 PM	4.2	4.1	3.9	4.0	4.2	4.1	0.1	3.2
8/8/96	7:45 AM	3.7	3.9	3.8	4.4	4.0	4.0	0.3	6.8
8/8/96	8:35 AM	3.5	4.0	4.2	3.5	4.0	3.8	0.3	8.4
8/8/96	9:25 AM	3.8	4.1	3.9	3.7	4.1	3.9	0.2	4.6
8/8/96	10:55 AM	3.6	3.6	4.0	4.0	3.3	3.7	0.3	8.1
8/8/96	11:50 AM	4.4	4.1	4.2	3.9	4.3	4.2	0.2	4.6
8/8/96	12:50 PM	4.3	4.4	3.8	3.8	4.3	4.1	0.3	7.2
8/8/96	2:00 PM	4.1	4.6	4.1	4.4	4.4	4.3	0.2	5.0
8/8/96	2:50 PM	3.7	4.1	3.6	4.4	3.8	3.9	0.3	8.3
8/8/96	3:50 PM	3.8	4.6	3.8	4.3	4.8	4.3	0.5	10.7
8/8/96	4:40 PM	4.3	4.5	4.0	4.1	3.5	4.1	0.4	9.2
8/8/96	5:35 PM	4.4	3.8	4.4	4.1	4.0	4.1	0.3	6.3
8/9/96	7:40 AM	3.8	3.9	4.0	4.1	3.8	3.9	0.1	3.3
8/9/96	8:35 AM	4.0	4.2	3.7	3.9	4.0	4.0	0.2	4.8
8/9/96	9:35 AM	4.2	4.3	3.8	3.7	4.0	4.0	0.3	6.4
8/9/96	10:45 AM	3.6	4.0	4.1	4.1	3.7	3.9	0.2	6.0
8/9/96	11:40 AM	3.8	4.1	4.0	4.4	4.4	4.1	0.3	6.3
8/9/96	12:30 PM	4.4	4.2	3.7	3.8	4.2	4.1	0.3	7.3
8/9/96	1:45 PM	4.2	4.6	3.6	3.6	4.5	3.9	0.4	10.0

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 6221A

Compression - Hardness (kp) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
8/3/96	12:50 PM	4.9	4.5	4.4	4.6	4.1	4.5	0.3	6.5
8/3/96	1:55 PM	3.6	4.0	3.8	4.2	3.6	3.8	0.3	6.8
8/3/96	2:45 PM	4.2	4.4	4.1	3.9	4.6	4.2	0.3	6.4
8/5/96	7:50 AM	3.7	3.9	3.7	3.5	4.0	3.8	0.2	5.2
8/5/96	8:45 AM	4.0	4.3	3.8	3.7	4.0	4.0	0.2	5.8
8/5/96	9:30 AM	4.5	3.3	3.5	3.5	4.3	3.8	0.5	14.1
8/5/96	10:20 AM	4.0	4.2	3.6	3.9	4.1	4.0	0.2	5.8
8/5/96	11:15 AM	4.0	3.6	3.3	4.0	3.7	3.7	0.3	7.9
8/5/96	12:20 PM	3.8	3.9	3.5	4.0	3.6	3.8	0.2	5.5
8/5/96	1:50 PM	4.0	3.9	3.5	4.4	3.6	3.9	0.4	9.2
8/5/96	3:45 PM	3.6	3.9	3.7	4.1	3.4	3.7	0.3	7.2
8/5/96	4:50 PM	3.8	3.4	3.6	3.6	3.9	3.7	0.2	5.3
8/5/96	5:50 PM	4.0	3.7	3.9	4.1	3.9	3.9	0.1	3.8
8/6/96	7:45 AM	3.2	2.8	3.5	3.5	3.1	3.2	0.3	9.2
8/6/96	8:45 AM	3.0	2.9	3.8	3.2	3.7	3.3	0.4	12.3
8/6/96	9:40 AM	3.9	3.4	3.8	3.9	3.2	3.6	0.3	8.8
8/6/96	10:55 AM	4.0	3.4	3.4	3.6	3.7	3.6	0.2	6.9
8/6/96	11:55 AM	3.5	3.8	3.7	3.5	3.3	3.6	0.2	5.5
8/6/96	12:50 PM	3.8	3.7	3.5	3.8	3.2	3.6	0.3	7.1
8/6/96	1:50 PM	3.3	3.4	3.6	3.5	3.3	3.4	0.1	3.8
8/6/96	2:50 PM	3.6	3.4	3.7	3.8	3.8	3.7	0.2	4.6
8/6/96	3:40 PM	3.6	3.7	3.7	3.9	4.1	3.8	0.2	5.3
8/6/96	4:40 PM	3.8	3.9	3.9	3.9	3.6	3.8	0.1	3.4
8/6/96	5:40 PM	3.5	3.7	3.4	3.6	3.9	3.6	0.2	5.3
8/7/96	7:45 AM	3.4	3.3	3.3	3.5	3.7	3.4	0.2	4.9
8/7/96	8:30 AM	3.3	3.5	3.3	3.3	3.6	3.4	0.1	4.2
8/7/96	9:40 AM	3.9	3.9	3.8	3.6	3.3	3.7	0.3	6.9
8/7/96	10:50 AM	3.9	3.7	3.5	3.6	3.9	3.7	0.2	4.8
8/7/96	11:50 AM	3.5	4.1	3.4	4.8	3.6	3.9	0.6	15.0
8/7/96	12:50 PM	3.5	3.8	4.3	4.1	3.9	3.9	0.3	7.7
8/7/96	1:50 PM	3.2	3.3	3.6	3.7	3.4	3.4	0.2	6.0
8/7/96	2:50 PM	3.9	3.3	3.9	3.5	3.6	3.6	0.3	7.2
8/7/96	3:45 PM	4.0	4.0	4.0	3.5	3.5	3.8	0.3	7.2
8/8/96	7:45 AM	3.5	3.7	4.2	3.4	3.6	3.7	0.3	8.5
8/8/96	8:35 AM	3.8	3.4	4.0	3.4	4.0	3.7	0.3	8.2
8/8/96	9:25 AM	3.9	3.3	3.5	3.7	3.7	3.6	0.2	6.3
8/8/96	10:55 AM	3.2	3.6	3.3	3.5	3.3	3.4	0.2	4.9
8/8/96	11:50 AM	3.6	3.8	3.4	3.1	3.9	3.6	0.3	9.0
8/8/96	12:50 PM	3.3	3.7	4.0	3.6	3.2	3.6	0.3	9.0
8/8/96	2:00 PM	3.5	3.3	3.9	3.8	3.7	3.6	0.2	6.6
8/8/96	2:50 PM	3.5	3.3	3.5	3.7	3.8	3.6	0.2	5.5
8/8/96	3:50 PM	3.6	3.8	4.8	3.9	4.1	4.0	0.5	11.4
8/8/96	4:40 PM	4.1	3.9	4.2	4.1	3.8	4.0	0.2	4.1
8/8/96	5:35 PM	3.2	3.8	4.0	3.6	4.3	3.8	0.4	11.0
8/9/96	7:40 AM	3.6	3.6	3.9	4.0	3.6	3.7	0.2	5.2
8/9/96	8:35 AM	3.6	3.6	3.7	3.4	3.4	3.5	0.1	3.8
8/9/96	9:35 AM	3.9	4.1	4.0	4.3	4.2	4.1	0.2	3.9
8/9/96	10:45 AM	3.6	3.5	3.5	3.8	4.0	3.7	0.2	5.9
8/9/96	11:40 AM	3.8	3.5	4.0	4.1	4.2	4.0	0.3	7.1
8/9/96	12:30 PM	4.2	3.8	4.1	4.3	3.8	4.0	0.2	5.7
8/9/96	1:45 PM	4.0	3.9	4.1	4.4	3.9	4.1	0.2	5.1

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 6250A

Compression - Hardness (kp) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
8/29/96	2:25 PM	4.9	4.8	5.1	5.6	5.1	5.1	0.3	6.0
8/29/96	3:25 PM	5.1	4.5	4.9	5.1	4.7	4.9	0.3	5.4
9/3/96	7:45 AM	4.2	4.1	3.6	4.0	4.8	4.1	0.4	10.5
9/3/96	9:00 AM	4.9	4.7	4.4	4.4	4.3	4.5	0.3	5.5
9/3/96	10:00 AM	4.8	4.9	4.4	4.9	4.9	4.8	0.2	4.5
9/3/96	11:00 AM	4.8	5.1	4.6	4.9	4.7	4.8	0.2	4.0
9/3/96	12:10 PM	4.9	4.7	5.1	4.9	4.5	4.8	0.2	4.7
9/3/96	1:10 PM	4.9	4.8	4.2	4.6	5.1	4.7	0.3	7.2
9/3/96	2:25 PM	5.5	4.8	4.7	4.8	4.6	4.9	0.4	7.3
9/3/96	3:30 PM	4.8	4.7	5.3	4.9	5.1	5.0	0.2	4.9
9/3/96	4:10 PM	4.6	4.6	4.4	4.5	5.1	4.6	0.3	5.8
9/3/96	5:10 PM	4.2	4.6	4.1	4.6	4.8	4.5	0.3	6.7
9/4/96	7:55 AM	4.9	4.7	4.5	4.6	4.9	4.7	0.2	3.8
9/4/96	8:55 AM	4.8	4.7	4.7	4.0	4.7	4.6	0.3	7.1
9/4/96	9:55 AM	4.4	4.8	4.0	4.6	4.6	4.5	0.3	6.8
9/4/96	11:10 AM	4.1	4.4	4.6	4.2	4.7	4.4	0.3	5.8
9/4/96	12:10 PM	4.6	4.6	4.7	5.0	4.5	4.7	0.2	4.1
9/4/96	1:00 PM	4.5	4.5	4.6	4.4	4.8	4.6	0.2	3.3
9/4/96	2:30 PM	4.8	4.2	4.7	4.5	4.4	4.5	0.2	5.3
9/4/96	3:30 PM	4.9	4.6	4.5	4.4	4.9	4.7	0.2	4.9
9/5/96	8:00 AM	4.9	4.7	4.2	5.0	4.8	4.7	0.3	6.6
9/5/96	9:00 AM	4.4	4.5	4.3	4.6	4.2	4.4	0.2	3.6
9/5/96	10:00 AM	4.5	4.3	4.8	4.9	4.6	4.6	0.2	5.2
9/5/96	10:55 AM	4.6	4.4	4.2	4.4	4.7	4.5	0.2	4.4
9/5/96	12:05 PM	4.1	4.1	4.6	4.7	4.3	4.4	0.3	6.4
9/5/96	1:00 PM	3.9	4.7	4.6	4.3	4.3	4.4	0.3	7.2
9/5/96	2:10 PM	4.2	3.8	4.4	4.0	4.0	4.1	0.2	5.6
9/5/96	3:00 PM	4.8	4.4	4.1	4.0	4.4	4.3	0.3	7.2
9/5/96	3:50 PM	4.4	4.0	3.8	4.3	4.1	4.1	0.2	5.8
9/5/96	4:50 PM	4.0	4.7	4.3	4.7	3.6	4.3	0.5	11.1
9/5/96	5:50 PM	3.7	3.7	4.0	4.5	4.5	4.1	0.4	9.9
9/6/96	8:00 AM	4.1	4.2	4.3	4.4	4.4	4.3	0.1	3.0
9/6/96	9:10 AM	4.3	4.2	4.5	4.1	4.0	4.2	0.2	4.6
9/6/96	10:10 AM	4.0	4.3	4.3	4.0	4.1	4.1	0.2	3.7
9/6/96	11:30 AM	3.9	4.1	4.1	4.2	4.0	4.1	0.1	2.8
9/6/96	12:20 PM	4.1	4.2	4.9	4.3	4.6	4.4	0.3	7.4
9/6/96	1:20 PM	4.4	4.3	4.5	4.5	4.7	4.5	0.1	3.3
9/6/96	2:25 PM	4.4	4.1	4.0	4.8	3.6	4.2	0.4	10.8
9/6/96	3:30 PM	3.8	4.2	4.1	4.5	3.8	4.1	0.3	7.2
9/7/96	7:25 AM	3.9	4.0	4.9	4.3	4.9	4.4	0.5	10.9
9/7/96	8:30 AM	3.9	4.4	4.2	4.2	4.4	4.2	0.2	4.9
9/7/96	9:30 AM	4.6	4.5	4.2	4.5	4.3	4.4	0.2	3.7
9/7/96	10:30 AM	4.0	4.3	3.6	3.8	4.6	4.1	0.4	9.8

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 6250A

Compression - Hardness (kp) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
8/29/96	2:25 PM	3.1	5.0	4.9	4.5	4.3	4.4	0.8	17.4
8/29/96	3:25 PM	4.7	4.7	4.3	4.8	4.5	4.6	0.2	4.3
9/3/96	7:45 AM	3.4	4.7	3.3	2.9	3.5	3.6	0.7	19.0
9/3/96	9:00 AM	4.3	3.8	4.3	4.0	3.6	4.0	0.3	7.7
9/3/96	10:00 AM	4.1	4.8	3.5	3.9	3.8	4.0	0.5	12.1
9/3/96	11:00 AM	4.7	4.2	4.1	4.5	3.7	4.2	0.4	9.1
9/3/96	12:10 PM	4.7	3.6	3.7	4.2	3.5	3.9	0.5	12.8
9/3/96	1:10 PM	3.9	4.6	3.8	4.6	3.9	4.2	0.4	9.7
9/3/96	2:25 PM	4.4	4.2	4.5	4.7	4.2	4.4	0.2	4.8
9/3/96	3:30 PM	4.5	4.3	4.2	4.0	4.1	4.2	0.2	4.6
9/3/96	4:10 PM	4.2	4.1	4.1	4.4	4.4	4.2	0.2	3.6
9/3/96	5:10 PM	4.2	4.0	3.8	4.6	4.4	4.2	0.3	7.5
9/4/96	7:55 AM	4.7	3.8	4.7	4.2	4.0	4.3	0.4	9.5
9/4/96	8:55 AM	3.5	3.9	4.2	4.0	4.2	4.0	0.3	7.3
9/4/96	9:55 AM	4.6	4.1	3.8	4.0	4.6	4.2	0.4	8.6
9/4/96	11:10 AM	4.5	3.8	4.4	4.4	4.8	4.4	0.4	8.3
9/4/96	12:10 PM	4.6	4.8	3.9	3.8	4.0	4.2	0.4	10.7
9/4/96	1:00 PM	4.1	4.7	4.4	4.3	4.4	4.4	0.2	4.9
9/4/96	2:30 PM	4.7	4.8	3.8	4.4	4.8	4.5	0.4	9.4
9/4/96	3:30 PM	3.9	4.1	4.4	4.2	4.2	4.3	0.2	4.6
9/5/96	8:00 AM	4.7	5.3	3.8	3.9	4.2	4.4	0.6	14.2
9/5/96	9:00 AM	4.3	4.1	4.1	3.9	4.2	4.1	0.1	3.6
9/5/96	10:00 AM	4.2	4.3	4.1	4.1	4.0	4.1	0.1	2.8
9/5/96	10:55 AM	4.5	4.2	3.9	3.7	4.1	4.1	0.3	7.4
9/5/96	12:05 PM	4.0	3.4	3.9	3.4	4.0	3.7	0.3	8.4
9/5/96	1:00 PM	3.5	3.9	4.1	4.6	4.2	4.1	0.4	9.9
9/5/96	2:10 PM	3.8	4.4	4.8	3.2	4.5	4.1	0.6	15.4
9/5/96	3:00 PM	4.1	4.6	4.4	4.0	4.5	4.3	0.3	6.0
9/5/96	3:50 PM	3.8	4.4	4.8	4.6	4.2	4.4	0.4	8.8
9/5/96	4:50 PM	4.6	3.8	4.0	4.1	3.8	4.1	0.3	8.1
9/5/96	5:50 PM	3.9	3.6	4.6	3.9	3.5	3.9	0.4	11.0
9/6/96	8:00 AM	3.8	4.1	4.0	4.2	4.0	4.0	0.1	3.7
9/6/96	9:10 AM	4.2	3.4	3.4	4.5	3.6	3.8	0.5	13.1
9/6/96	10:10 AM	4.1	4.1	4.0	3.8	3.5	3.9	0.3	6.5
9/6/96	11:30 AM	4.4	6.0	3.8	4.0	3.8	4.4	0.9	21.1
9/6/96	12:20 PM	4.2	3.6	4.3	3.9	3.6	3.9	0.3	8.3
9/6/96	1:20 PM	4.2	4.5	3.9	4.4	4.0	4.2	0.3	6.1
9/6/96	2:25 PM	3.7	4.2	3.6	4.3	3.8	3.9	0.3	7.9
9/6/96	3:30 PM	4.1	3.8	4.1	4.1	4.2	4.1	0.2	3.7
9/7/96	7:25 AM	4.5	4.8	3.9	4.8	4.9	4.6	0.4	8.9
9/7/96	8:30 AM	3.7	3.9	4.1	4.1	4.2	4.0	0.2	5.0
9/7/96	9:30 AM	3.8	3.4	3.8	4.4	3.8	3.8	0.4	9.3
9/7/96	10:30 AM	4.4	4.8	3.9	4.1	4.4	4.3	0.3	7.9

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 6221A

Compression - Thickness (mm) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
8/3/96	12:50 PM	2.58	2.58	2.59	2.56	2.59	2.58	0.01	0.5
8/3/96	1:55 PM	2.57	2.58	2.59	2.57	2.56	2.57	0.01	0.4
8/3/96	2:45 PM	2.60	2.55	2.58	2.57	2.61	2.58	0.02	0.9
8/5/96	7:50 AM	2.62	2.60	2.65	2.60	2.60	2.61	0.02	0.8
8/5/96	8:45 AM	2.58	2.62	2.63	2.58	2.60	2.60	0.02	0.9
8/5/96	9:30 AM	2.60	2.59	2.58	2.59	2.60	2.58	0.02	0.8
8/5/96	10:20 AM	2.60	2.59	2.61	2.60	2.60	2.60	0.01	0.3
8/5/96	11:15 AM	2.63	2.60	2.62	2.63	2.63	2.62	0.01	0.5
8/5/96	12:20 PM	2.62	2.58	2.58	2.54	2.56	2.58	0.03	1.2
8/5/96	1:50 PM	2.57	2.61	2.56	2.58	2.65	2.59	0.04	1.4
8/5/96	3:45 PM	2.61	2.63	2.62	2.65	2.58	2.62	0.03	1.3
8/5/96	4:50 PM	2.57	2.60	2.61	2.53	2.60	2.58	0.03	1.3
8/5/96	5:50 PM	2.65	2.62	2.65	2.64	2.58	2.63	0.03	1.1
8/6/96	7:45 AM	2.60	2.62	2.59	2.61	2.64	2.61	0.02	0.7
8/6/96	8:45 AM	2.62	2.65	2.56	2.62	2.58	2.61	0.04	1.4
8/6/96	9:40 AM	2.63	2.61	2.59	2.57	2.61	2.60	0.02	0.9
8/6/96	10:55 AM	2.64	2.63	2.62	2.56	2.65	2.62	0.04	1.3
8/6/96	11:55 AM	2.63	2.61	2.79	2.58	2.57	2.64	0.09	3.4
8/6/96	12:50 PM	2.60	2.61	2.62	2.61	2.59	2.61	0.01	0.4
8/6/96	1:50 PM	2.65	2.58	2.60	2.59	2.63	2.61	0.03	1.1
8/6/96	2:50 PM	2.60	2.62	2.63	2.66	2.65	2.63	0.02	0.9
8/6/96	3:40 PM	2.65	2.68	2.62	2.60	2.59	2.63	0.04	1.4
8/6/96	4:40 PM	2.67	2.62	2.63	2.62	2.62	2.63	0.02	0.8
8/6/96	5:40 PM	2.63	2.58	2.64	2.59	2.61	2.61	0.03	1.0
8/7/96	7:45 AM	2.60	2.65	2.64	2.65	2.64	2.64	0.02	0.8
8/7/96	8:30 AM	2.61	2.62	2.64	2.58	2.62	2.61	0.02	0.8
8/7/96	9:40 AM	2.62	2.57	2.62	2.62	2.67	2.62	0.04	1.4
8/7/96	10:50 AM	2.65	2.61	2.58	2.61	2.61	2.61	0.02	1.0
8/7/96	11:50 AM	2.64	2.63	2.58	2.61	2.64	2.62	0.03	1.0
8/7/96	12:50 PM	2.62	2.58	2.59	2.58	2.63	2.60	0.02	0.9
8/7/96	1:50 PM	2.58	2.56	2.56	2.60	2.61	2.58	0.02	0.9
8/7/96	2:50 PM	2.62	2.59	2.62	2.65	2.65	2.63	0.03	1.0
8/7/96	3:45 PM	2.61	2.62	2.59	2.60	2.61	2.61	0.01	0.4
8/8/96	7:45 AM	2.62	2.64	2.61	2.62	2.64	2.63	0.01	0.5
8/8/96	8:35 AM	2.61	2.59	2.60	2.60	2.62	2.60	0.01	0.4
8/8/96	9:25 AM	2.65	2.62	2.62	2.60	2.58	2.61	0.03	1.0
8/8/96	10:55 AM	2.61	2.61	2.60	2.62	2.59	2.61	0.01	0.4
8/8/96	11:50 AM	2.62	2.61	2.63	2.62	2.61	2.62	0.01	0.3
8/8/96	12:50 PM	2.65	2.64	2.61	2.60	2.62	2.62	0.02	0.8
8/8/96	2:00 PM	2.64	2.61	2.61	2.65	2.63	2.63	0.02	0.7
8/8/96	2:50 PM	2.58	2.56	2.63	2.62	2.65	2.61	0.04	1.4
8/8/96	3:50 PM	2.61	2.63	2.60	2.59	2.62	2.61	0.02	0.6
8/8/96	4:40 PM	2.60	2.65	2.58	2.61	2.62	2.61	0.03	1.0
8/8/96	5:35 PM	2.59	2.61	2.63	2.60	2.62	2.61	0.02	0.8
8/9/96	7:40 AM	2.60	2.62	2.64	2.66	2.62	2.61	0.02	0.6
8/9/96	8:35 AM	2.62	2.63	2.60	2.64	2.61	2.62	0.02	0.6
8/9/96	9:35 AM	2.60	2.61	2.62	2.64	2.63	2.62	0.02	0.6
8/9/96	10:45 AM	2.62	2.64	2.65	2.62	2.58	2.62	0.03	1.0
8/9/96	11:40 AM	2.62	2.66	2.60	2.60	2.60	2.65	0.03	1.1
8/9/96	12:30 PM	2.61	2.63	2.64	2.63	2.62	2.63	0.01	0.4
8/9/96	1:45 PM	2.58	2.60	2.61	2.64	2.62	2.61	0.02	0.9

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 6221A

Compression - Thickness (mm) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
8/3/96	12:50 PM	2.61	2.62	2.70	2.65	2.64	2.64	0.04	1.3
8/3/96	1:55 PM	2.62	2.60	2.57	2.60	2.59	2.60	0.02	0.7
8/3/96	2:45 PM	2.60	2.62	2.70	2.64	2.68	2.65	0.04	1.6
8/5/96	7:50 AM	2.60	2.68	2.65	2.60	2.65	2.64	0.04	1.3
8/5/96	8:45 AM	2.62	2.68	2.64	2.61	2.59	2.63	0.03	1.3
8/5/96	9:30 AM	2.63	2.62	2.63	2.61	2.65	2.65	0.01	0.6
8/5/96	10:20 AM	2.69	2.65	2.63	2.63	2.65	2.65	0.02	0.9
8/5/96	11:15 AM	2.61	2.64	2.63	2.66	2.58	2.62	0.03	1.2
8/5/96	12:20 PM	2.59	2.63	2.59	2.63	2.62	2.61	0.02	0.8
8/5/96	1:50 PM	2.64	2.61	2.62	2.61	2.61	2.62	0.01	0.5
8/5/96	3:45 PM	2.62	2.61	2.61	2.62	2.66	2.62	0.02	0.8
8/5/96	4:50 PM	2.62	2.60	2.61	2.62	2.67	2.62	0.03	1.0
8/5/96	5:50 PM	2.67	2.63	2.59	2.65	2.63	2.63	0.03	1.1
8/6/96	7:45 AM	2.65	2.63	2.62	2.67	2.66	2.65	0.02	0.8
8/6/96	8:45 AM	2.58	2.60	2.62	2.64	2.62	2.61	0.02	0.9
8/6/96	9:40 AM	2.61	2.68	2.64	2.62	2.69	2.65	0.04	1.3
8/6/96	10:55 AM	2.59	2.61	2.63	2.62	2.60	2.61	0.02	0.6
8/6/96	11:55 AM	2.62	2.67	2.65	2.65	2.62	2.64	0.02	0.8
8/6/96	12:50 PM	2.62	2.65	2.68	2.63	2.68	2.65	0.03	1.0
8/6/96	1:50 PM	2.63	2.62	2.64	2.63	2.62	2.63	0.01	0.3
8/6/96	2:50 PM	2.65	2.61	2.65	2.67	2.65	2.65	0.02	0.8
8/6/96	3:40 PM	2.61	2.65	2.62	2.65	2.68	2.64	0.03	1.1
8/6/96	4:40 PM	2.64	2.63	2.68	2.62	2.61	2.64	0.03	1.0
8/6/96	5:40 PM	2.64	2.62	2.67	2.62	2.60	2.63	0.03	1.0
8/7/96	7:45 AM	2.63	2.58	2.61	2.58	2.64	2.61	0.03	1.1
8/7/96	8:30 AM	2.62	2.63	2.60	2.64	2.62	2.62	0.01	0.6
8/7/96	9:40 AM	2.60	2.66	2.66	2.60	2.63	2.63	0.03	1.1
8/7/96	10:50 AM	2.73	2.66	2.62	2.60	2.62	2.65	0.05	2.0
8/7/96	11:50 AM	2.62	2.63	2.63	2.64	2.61	2.63	0.01	0.4
8/7/96	12:50 PM	2.63	2.65	2.66	2.63	2.65	2.64	0.01	0.5
8/7/96	1:50 PM	2.60	2.61	2.58	2.61	2.63	2.61	0.02	0.7
8/7/96	2:50 PM	2.60	2.62	2.65	2.61	2.63	2.62	0.02	0.7
8/7/96	3:45 PM	2.65	2.68	2.68	2.67	2.69	2.67	0.02	0.6
8/8/96	7:45 AM	2.65	2.66	2.68	2.68	2.65	2.66	0.02	0.6
8/8/96	8:35 AM	2.64	2.65	2.67	2.62	2.64	2.64	0.02	0.7
8/8/96	9:25 AM	2.62	2.60	2.63	2.65	2.63	2.63	0.02	0.7
8/8/96	10:55 AM	2.61	2.63	2.60	2.61	2.59	2.61	0.01	0.6
8/8/96	11:50 AM	2.65	2.64	2.62	2.60	2.59	2.62	0.03	1.0
8/8/96	12:50 PM	2.60	2.62	2.58	2.68	2.58	2.61	0.04	1.6
8/8/96	2:00 PM	2.62	2.64	2.61	2.63	2.64	2.63	0.01	0.5
8/8/96	2:50 PM	2.63	2.56	2.62	2.57	2.60	2.60	0.03	1.2
8/8/96	3:50 PM	2.62	2.60	2.61	2.64	2.63	2.62	0.02	0.6
8/8/96	4:40 PM	2.62	2.60	2.63	2.63	2.60	2.62	0.02	0.6
8/8/96	5:35 PM	2.60	2.61	2.62	2.58	2.60	2.60	0.01	0.6
8/9/96	7:40 AM	2.56	2.60	2.59	2.58	2.61	2.59	0.02	0.7
8/9/96	8:35 AM	2.58	2.60	2.61	2.58	2.63	2.60	0.02	0.8
8/9/96	9:35 AM	2.63	2.66	2.62	2.63	2.62	2.63	0.02	0.6
8/9/96	10:45 AM	2.62	2.63	2.60	2.64	2.59	2.62	0.02	0.8
8/9/96	11:40 AM	2.62	2.63	2.58	2.60	2.61	2.61	0.02	0.7
8/9/96	12:30 PM	2.58	2.59	2.57	2.61	2.63	2.60	0.02	0.9
8/9/96	1:45 PM	2.62	2.61	2.59	2.63	2.64	2.62	0.02	0.7

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 6250A

Compression - Thickness (mm) - Front

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
8/29/96	2:25 PM	2.62	2.63	2.65	2.67	2.64	2.64	0.02	0.7
8/29/96	3:25 PM	2.56	2.60	2.62	2.61	2.59	2.60	0.02	0.9
9/3/96	7:45 AM	2.58	2.57	2.60	2.61	2.57	2.59	0.02	0.7
9/3/96	9:00 AM	2.62	2.64	2.58	2.58	2.60	2.60	0.03	1.0
9/3/96	10:00 AM	2.60	2.63	2.62	2.60	2.64	2.62	0.02	0.7
9/3/96	11:00 AM	2.65	2.62	2.62	2.63	2.66	2.64	0.02	0.7
9/3/96	12:10 PM	2.60	2.61	2.65	2.56	2.58	2.60	0.03	1.3
9/3/96	1:10 PM	2.67	2.67	2.65	2.62	2.68	2.66	0.02	0.9
9/3/96	2:25 PM	2.61	2.62	2.64	2.62	2.58	2.61	0.02	0.8
9/3/96	3:30 PM	2.60	2.65	2.63	2.65	2.68	2.64	0.03	1.1
9/3/96	4:10 PM	2.63	2.57	2.65	2.60	2.58	2.61	0.03	1.3
9/3/96	5:10 PM	2.65	2.58	2.60	2.55	2.56	2.59	0.04	1.5
9/4/96	7:55 AM	2.63	2.62	2.65	2.58	2.60	2.62	0.03	1.0
9/4/96	8:55 AM	2.55	2.57	2.61	2.61	2.62	2.59	0.03	1.2
9/4/96	9:55 AM	2.53	2.58	2.58	2.60	2.58	2.57	0.03	1.0
9/4/96	11:10 AM	2.58	2.58	2.57	2.52	2.59	2.57	0.03	1.1
9/4/96	12:10 PM	2.60	2.58	2.56	2.60	2.59	2.59	0.02	0.6
9/4/96	1:00 PM	2.57	2.59	2.56	2.57	2.55	2.57	0.01	0.6
9/4/96	2:30 PM	2.56	2.56	2.62	2.55	2.58	2.57	0.03	1.1
9/4/96	3:30 PM	2.58	2.58	2.62	2.56	2.60	2.59	0.02	0.9
9/5/96	8:00 AM	2.58	2.57	2.62	2.60	2.64	2.60	0.03	1.1
9/5/96	9:00 AM	2.58	2.58	2.57	2.59	2.60	2.58	0.01	0.4
9/5/96	10:00 AM	2.57	2.61	2.59	2.61	2.59	2.59	0.02	0.6
9/5/96	10:55 AM	2.56	2.55	2.53	2.57	2.58	2.56	0.02	0.8
9/5/96	12:05 PM	2.54	2.61	2.61	2.57	2.57	2.58	0.03	1.2
9/5/96	1:00 PM	2.57	2.55	2.59	2.58	2.57	2.57	0.01	0.6
9/5/96	2:10 PM	2.54	2.55	2.61	2.56	2.61	2.57	0.03	1.0
9/5/96	3:00 PM	2.60	2.53	2.50	2.59	2.56	2.56	0.04	1.6
9/5/96	3:50 PM	2.60	2.62	2.53	2.57	2.56	2.58	0.04	1.4
9/5/96	4:50 PM	2.53	2.51	2.60	2.67	2.56	2.57	0.06	2.5
9/5/96	5:50 PM	2.50	2.54	2.60	2.58	2.54	2.55	0.04	1.5
9/6/96	8:00 AM	2.60	2.55	2.58	2.54	2.59	2.57	0.03	1.0
9/6/96	9:10 AM	2.56	2.54	2.58	2.57	2.60	2.57	0.02	0.9
9/6/96	10:10 AM	2.52	2.56	2.58	2.53	2.56	2.55	0.02	1.0
9/6/96	11:30 AM	2.52	2.56	2.55	2.55	2.51	2.54	0.02	0.9
9/6/96	12:20 PM	2.62	2.58	2.55	2.56	2.55	2.57	0.03	1.1
9/6/96	1:20 PM	2.55	2.53	2.56	2.55	2.54	2.55	0.01	0.4
9/6/96	2:25 PM	2.53	2.55	2.55	2.54	2.56	2.55	0.01	0.4
9/6/96	3:30 PM	2.60	2.56	2.58	2.60	2.62	2.59	0.02	0.9
9/7/96	7:25 AM	2.59	2.62	2.55	2.54	2.56	2.57	0.03	1.3
9/7/96	8:30 AM	2.68	2.62	2.59	2.60	2.61	2.62	0.04	1.3
9/7/96	9:30 AM	2.55	2.60	2.55	2.62	2.60	2.58	0.03	1.2
9/7/96	10:30 AM	2.51	2.58	2.60	2.60	2.52	2.56	0.04	1.7

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION

DIGOXIN TABLETS, 0.125 mg - Batch # 6250A

Compression - Thickness (mm) - Rear

Date	Time	1	2	3	4	5	Average	St Dev.	RSD
8/29/96	2:25 PM	2.54	2.56	2.55	2.55	2.60	2.56	0.02	0.9
8/29/96	3:25 PM	2.54	2.60	2.59	2.58	2.57	2.58	0.02	0.9
9/3/96	7:45 AM	2.60	2.56	2.56	2.54	2.53	2.56	0.03	1.0
9/3/96	9:00 AM	2.55	2.50	2.59	2.48	2.55	2.53	0.04	1.7
9/3/96	10:00 AM	2.50	2.57	2.57	2.53	2.60	2.55	0.04	1.5
9/3/96	11:00 AM	2.58	2.55	2.57	2.51	2.53	2.55	0.03	1.1
9/3/96	12:10 PM	2.56	2.58	2.60	2.58	2.61	2.59	0.02	0.8
9/3/96	1:10 PM	2.59	2.59	2.60	2.61	2.59	2.60	0.01	0.3
9/3/96	2:25 PM	2.61	2.62	2.57	2.63	2.63	2.59	0.04	1.6
9/3/96	3:30 PM	2.57	2.61	2.63	2.62	2.59	2.60	0.02	0.9
9/3/96	4:10 PM	2.62	2.60	2.58	2.59	2.60	2.60	0.01	0.6
9/3/96	5:10 PM	2.62	2.59	2.60	2.59	2.61	2.60	0.01	0.5
9/4/96	7:55 AM	2.62	2.60	2.58	2.62	2.59	2.60	0.02	0.7
9/4/96	8:55 AM	2.60	2.58	2.57	2.57	2.61	2.59	0.02	0.7
9/4/96	9:55 AM	2.65	2.62	2.60	2.55	2.58	2.60	0.04	1.5
9/4/96	11:10 AM	2.58	2.60	2.55	2.56	2.56	2.57	0.02	0.8
9/4/96	12:10 PM	2.56	2.67	2.62	2.57	2.64	2.61	0.05	1.8
9/4/96	1:00 PM	2.59	2.61	2.67	2.65	2.68	2.64	0.04	1.5
9/4/96	2:30 PM	2.58	2.54	2.62	2.56	2.60	2.58	0.03	1.2
9/4/96	3:30 PM	2.55	2.56	2.54	2.58	2.56	2.56	0.01	0.6
9/5/96	8:00 AM	2.71	2.65	2.72	2.71	2.64	2.69	0.04	1.4
9/5/96	9:00 AM	2.58	2.60	2.58	2.59	2.61	2.59	0.01	0.5
9/5/96	10:00 AM	2.62	2.62	2.57	2.62	2.59	2.60	0.02	0.9
9/5/96	10:55 AM	2.58	2.60	2.65	2.60	2.64	2.61	0.03	1.1
9/5/96	12:05 PM	2.56	2.47	2.51	2.51	2.60	2.53	0.05	2.0
9/5/96	1:00 PM	2.62	2.54	2.65	2.56	2.52	2.58	0.05	2.1
9/5/96	2:10 PM	2.60	2.61	2.50	2.55	2.49	2.55	0.06	2.2
9/5/96	3:00 PM	2.60	2.63	2.68	2.60	2.55	2.61	0.05	1.8
9/5/96	3:50 PM	2.59	2.60	2.58	2.57	2.59	2.59	0.01	0.4
9/5/96	4:50 PM	2.56	2.57	2.63	2.57	2.58	2.58	0.03	1.1
9/5/96	5:50 PM	2.56	2.54	2.56	2.55	2.57	2.56	0.01	0.4
9/6/96	8:00 AM	2.58	2.60	2.59	2.60	2.58	2.59	0.01	0.4
9/6/96	9:10 AM	2.53	2.56	2.58	2.55	2.61	2.57	0.03	1.2
9/6/96	10:10 AM	2.53	2.59	2.56	2.56	2.50	2.55	0.03	1.3
9/6/96	11:30 AM	2.55	2.65	2.58	2.58	2.59	2.59	0.04	1.4
9/6/96	12:20 PM	2.53	2.54	2.56	2.53	2.58	2.55	0.02	0.9
9/6/96	1:20 PM	2.62	2.55	2.58	2.56	2.57	2.58	0.03	1.0
9/6/96	2:25 PM	2.51	2.55	2.60	2.55	2.55	2.55	0.03	1.3
9/6/96	3:30 PM	2.50	2.58	2.56	2.56	2.55	2.55	0.03	1.2
9/7/96	7:25 AM	2.58	2.62	2.58	2.62	2.61	2.60	0.02	0.8
9/7/96	8:30 AM	2.60	2.59	2.60	2.58	2.60	2.59	0.01	0.3
9/7/96	9:30 AM	2.55	2.52	2.60	2.59	2.62	2.58	0.04	1.6
9/7/96	10:30 AM	2.57	2.55	2.60	2.58	2.62	2.58	0.03	1.0

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION*****DIGOXIN TABLETS, 0.125 mg***

Compression - Friability (%)

Batch #	6221A	6221A	6250A	6250A	6250A	Front	Rear
Side	Front	Rear	Front	Rear	Front	Front	Rear
1st Third	0.1	0.1	0.1	0.1	0.1		
2nd Third	0.1	0.1	0.1	0.1	0.1		
Final Third	0.1	0.1	0.1	0.1	0.1		
Average	0.1	0.1	0.1	0.1	0.1		
St Dev.	0.0	0.0	0.0	0.0	0.0		
RSD	0.0	0.0	0.0	0.0	0.0		

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION****DIGOXIN TABLETS, 0.125 mg**

Compression - Content Uniformity (%)

Batch #	6221A	6221A	6250A	6250A	Front	Rear
Side	Front	Rear	Front	Rear	Front	Rear
1	100.0	102.8	103.0	102.2		
2	103.5	100.4	103.2	104.0		
3	100.5	103.7	103.1	99.9		
4	102.0	101.0	105.0	100.7		
5	100.4	101.9	100.3	102.1		
6	102.3	102.1	101.1	101.8		
7	104.4	100.4	100.8	102.2		
8	99.5	102.0	99.2	102.6		
9	103.0	100.8	99.8	101.6		
10	100.7	102.0	99.5	102.4		
11	101.1	102.1	101.5	101.6		
12	98.1	103.4	101.6	102.8		
13	100.3	100.6	101.5	100.1		
14	101.1	102.3	100.0	100.3		
15	101.9	100.5	98.9	101.8		
16	98.6	102.1	98.9	101.9		
17	100.7	100.7	98.5	101.9		
18	101.9	100.8	97.8	102.0		
19	101.7	102.3	98.2	100.7		
20	98.6	100.6	97.5	102.9		
21	103.8	103.4	101.6	102.3		
22	102.6	100.6	101.3	102.7		
23	100.5	100.7	102.8	100.1		
24	100.7	102.1	100.2	100.9		
25	100.5	103.5	98.6	102.7		
26	99.0	103.5	100.2	101.8		
27	100.2	102.3	100.3	101.9		
28	98.6	103.6	98.4	102.7		
29	101.5	101.9	99.3	100.9		
30	102.4	100.7	99.1	101.8		
Average	101.0	101.8	100.4	101.8		
St Dev.	1.6	1.1	1.8	1.0		
RSD	1.6	1.1	1.8	0.9		

AMIDE PHARMACEUTICAL, INC.**PROCESS VALIDATION*****DIGOXIN TABLETS, 0.125 mg***

Compression - Dissolution (% Released)

Batch #	6221A	6221A	6221A	6221A	6250A	6250A	6250A	6250A	6250A
Time	15 min	15 min	60 min	60 min	15 min	15 min	60 min	60 min	60 min
Side	Front	Rear	Front	Rear	Front	Rear	Front	Rear	Front
1	80.1	86.7	94.5	99.5	84.5	80.4	96.7	97.1	97.1
2	80.4	88.3	98.2	102.5	83.9	82.1	98.9	101.6	101.6
3	85.5	88.3	99.9	99.9	85.0	85.3	99.0	104.4	104.4
4	83.2	85.3	97.4	100.5	85.1	82.8	98.2	99.0	99.0
5	83.3	86.1	100.9	99.1	85.6	80.4	97.4	98.1	98.1
6	83.2	86.4	98.6	101.9	82.7	83.4	96.6	101.6	101.6
7	83.7	85.2	100.6	97.2	83.1	77.3	95.6	92.7	92.7
8	83.9	85.0	97.2	98.7	81.7	83.7	95.9	98.5	98.5
9	80.9	86.2	97.0	96.6	80.9	81.7	99.3	96.8	96.8
10	81.3	86.9	100.4	97.7	81.5	83.1	98.7	96.6	96.6
11	81.7	87.8	100.9	99.6	82.4	79.8	96.9	95.6	95.6
12	81.6	87.3	100.0	97.7	82.5	79.7	97.9	92.4	92.4
Average	82.4	86.6	98.8	99.2	83.2	81.6	97.6	97.9	97.9
St Dev.	1.6	1.1	2.0	1.8	1.6	2.2	1.3	3.5	3.5
RSD	2.0	1.3	2.0	1.8	1.9	2.7	1.3	3.6	3.6

Amide Pharmaceutical, Inc.

Page 1 of 2

LABORATORY TEST REPORT**FINISHED DRUG PRODUCT**PRODUCT: Digoxin Tablets, 0.125 mgSPECIFICATION: USP MOI #: 145 REVISION #: 01 BATCH #: 6221ACHEMIST: LS/PA VOLUME #: 303 05 PAGE #: 251-259/177 DATE: 8/14/96SAMPLE STAGE: Compression (Composite Sample)

8/14/96

TEST	RESULT	LIMIT
DESCRIPTION: Color:	<u>yellow</u>	Yellow
Profile:	<u>Round bisected tablet</u>	Round bisected tablets
Other: Debossed		o "A 145" on bisected side
	<u>"dp 970" on bisected side</u>	o "dp 970" on bisected side
FRIABILITY:	<u>0.03 %</u>	NMT 1.0 %
IDENTIFICATION: (A)	<u>The retention time of the major peak in the chromatogram of Assay corresponds to standard preparation.</u>	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.
ASSAY: Digoxin, 0.125 mg	<u>100.7 %</u>	90.0% - 105.0%
UNIFORMITY OF DOSAGE UNITS: (Content Uniformity) Digoxin, 0.125 mg	1) <u>102.0 %</u> 6) <u>102.8 %</u> 2) <u>100.4 %</u> 7) <u>103.0 %</u> 3) <u>102.7 %</u> 8) <u>102.9 %</u> 4) <u>98.8 %</u> 9) <u>102.1 %</u> 5) <u>102.1 %</u> 10) <u>101.6 %</u> AV: <u>101.9 %</u> RSD: <u>1.3 %</u>	85.0% to 115.0%
() COMPLIES	PREPARED BY: <u>Nilesh Patel</u>	DATE: <u>6/20/96</u>
() DOES NOT COMPLY	APPROVED BY: <u>Swyabhar Patel</u>	DATE: <u>6/20/96</u>

QC19 145c

Amide Pharmaceutical, Inc.

Page 2 of 2

LABORATORY TEST REPORT**FINISHED DRUG PRODUCT**PRODUCT: Digoxin Tablets, 0.125 mgSPECIFICATION: USP MOI #: 145 REVISION #: 01 BATCH #: 6221 ACHEMIST: PA VOLUME #: 332-2 PAGE #: 122 DATE: 8/14/96SAMPLE STAGE: Compression (Compressible sample) 8/14/96

TEST	RESULT	LIMIT
DISSOLUTION: Media: 500mL 0.1N HCl Appar: I, rpm: 120 Temp: 37°C ± 0.5°C Time: 60 minutes	15 minutes: 1) <u>81.7</u> % 7) <u>80.8</u> % 2) <u>81.5</u> % 8) <u>81.6</u> % 3) <u>81.7</u> % 9) <u>81.0</u> % 4) <u>81.6</u> % 10) <u>83.1</u> % 5) <u>80.2</u> % 11) <u>84.7</u> % 6) <u>77.7</u> % 12) <u>82.0</u> % Average: <u>81.7</u> % 60 minutes: 1) <u>73.4</u> % 7) <u>72.3</u> % 2) <u>78.5</u> % 8) <u>74.5</u> % 3) <u>76.6</u> % 9) <u>73.0</u> % 4) <u>75.0</u> % 10) <u>76.5</u> % 5) <u>74.6</u> % 11) <u>76.6</u> % 6) <u>73.3</u> % 12) <u>73.0</u> % Average: <u>74.8</u> %	(Note - The specified tolerances are for % dissolved, and are not to be interpreted as Q values.) NLT 80% of the LC of Digoxin dissolved in 60 minutes for the average of 12 tablets tested and no individual tablet has less than 75% of the LC of Digoxin dissolved in 60 minutes. If the amount of Digoxin dissolved in 60 minutes is more than 95% for any individual Tablet, the amount dissolved in 15 minutes is not more than 90% for each individual Tablet. (LC: Labeled amount)
(X) COMPLIES	PREPARED BY: <u>W. L. Patel</u> DATE: <u>8/16/96</u>	
() DOES NOT COMPLY	APPROVED BY: <u>S. J. Patel</u> DATE: <u>8/20/96</u>	

0019 145d

Amide Pharmaceutical, Inc.

Page 1 of 2

LABORATORY TEST REPORT**FINISHED DRUG PRODUCT**PRODUCT: Digoxin Tablets, 0.125 mgSPECIFICATION: USP MOI #: 145 REVISION #: 01 BATCH #: 6250ACHEMIST: C.D.P.R.J VOLUME #: 343-00 PAGE #: 87, 243 DATE: 9-11-96SAMPLE STAGE: Overall Composite sample dated 9-10-96

TEST	RESULT	LIMIT
DESCRIPTION: Color:	<u>Yellow</u>	Yellow
Profile:	<u>round bisected tablets</u>	Round bisected tablets
Other: Debossed	<u>"A145" on bisected side</u>	<input checked="" type="checkbox"/> "A 145" on bisected side <input type="checkbox"/> "dp 970" on bisected side
FRIABILITY:	<u>0.02 %</u>	NMT 1.0 %
IDENTIFICATION: (A)	<u>The retention time of the major peak in the chromatogram of assay prepn. Corresponds to Evol. prep.</u>	The retention time of the major peak in the chromatogram of Assay preparation corresponds to standard preparation.
ASSAY: Digoxin, 0.125 mg	<u>101.1 %</u>	90.0% - 105.0%
UNIFORMITY OF DOSAGE UNITS: (Content Uniformity) Digoxin, 0.125 mg	1) <u>102.1 %</u> 6) <u>101.6 %</u> 2) <u>103.2 %</u> 7) <u>101.5 %</u> 3) <u>102.5 %</u> 8) <u>100.3 %</u> 4) <u>102.1 %</u> 9) <u>100.7 %</u> 5) <u>101.3 %</u> 10) <u>101.4 %</u> AV: <u>101.7</u> RSD: <u>0.8</u>	85.0% to 115.0% <div style="border: 1px solid black; padding: 5px; text-align: center;"> APPROVED <u>BY S.D.</u> DATE <u>9/11/96</u> RSD: NMT 6.0% </div>
(<input checked="" type="checkbox"/>) COMPLIES	PREPARED BY: <u>Nilesh Patel</u>	DATE: <u>6/20/96</u>
() DOES NOT COMPLY	APPROVED BY: <u>Suryakant Patel</u>	DATE: <u>6/20/96</u>

QC19-145c

Amide Pharmaceutical, Inc.

Page 2 of 2

LABORATORY TEST REPORT**FINISHED DRUG PRODUCT**PRODUCT: Digoxin Tablets, 0.125 mgSPECIFICATION: USP MOI #: 145 REVISION #: 01 BATCH #: 6250ACHEMIST: CDP, RJ VOLUME #: 343-00 PAGE #: 87, 243 DATE: 9-11-96SAMPLE STAGE: Overall Composite sample dated 9-10-96

TEST	RESULT	LIMIT
DISSOLUTION: Media: 500mL 0.1N HCl Appar: I, rpm: 120 Temp: 37°C ± 0.5°C Time: 60 minutes	15 minutes: 1) <u>78.9</u> % 7) <u>78.3</u> % 2) <u>79.6</u> % 8) <u>80.7</u> % 3) <u>77.1</u> % 9) <u>81.2</u> % 4) <u>82.5</u> % 10) <u>76.7</u> % 5) <u>78.8</u> % 11) <u>80.2</u> % 6) <u>77.6</u> % 12) <u>77.6</u> % Average: <u>79.1</u> % 60 minutes: 1) <u>97.2</u> % 7) <u>93.2</u> % 2) <u>94.3</u> % 8) <u>92.1</u> % 3) <u>92.6</u> % 9) <u>92.6</u> % 4) <u>101.7</u> % 10) <u>92.2</u> % 5) <u>96.6</u> % 11) <u>95.3</u> % 6) <u>90.9</u> % 12) <u>95.8</u> % Average: <u>94.5</u> %	(Note - The specified tolerances are for % dissolved, and are not to be interpreted as Q values.) NLT 80% of the LC of Digoxin dissolved in 60 minutes for the average of 12 tablets tested and no individual tablet has less than 75% of the LC of Digoxin dissolved in 60 minutes. If the amount of Digoxin dissolved in 60 minutes is more than 95% for any individual Tablet, the amount dissolved in 15 minutes is not more than 90% for each individual Tablet. (LC: Labeled amount)
<input checked="" type="checkbox"/> COMPLIES <input type="checkbox"/> DOES NOT COMPLY	PREPARED BY: <u>Nilesh Patel</u> DATE: <u>6/26/96</u> APPROVED BY: <u>Suryakant Patel</u> DATE: <u>6/20/96</u>	<div style="border: 1px solid black; padding: 5px; text-align: center;"> APPROVED <u>WSD</u> <u>9/11/96</u> </div>

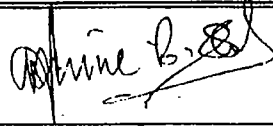
QC19-145d

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL

DIGOXIN TABLETS 0.125 mg
MPR NO. 14504 REV. 00
PROTOCOL NO: 14504-01
BATCH SIZE: 4,800,000 TABLETS

PREPARED BY:

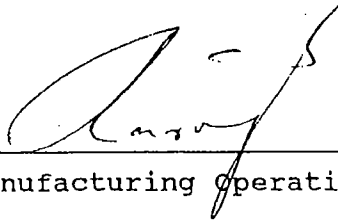


Regulatory Affairs Director

DATE:

7/26/95

APPROVED BY:



Manufacturing Operations Director

DATE:

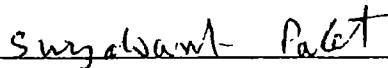
7/26/95



Quality Assurance Director

DATE:

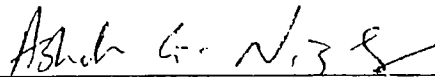
7/27/95



Quality Control Director

DATE:

7/27/95



Vice President Operations

DATE:

7-27-95

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
MPR NO. 14504 REV.00 PROTOCOL NO: 14504-01

PURPOSE:

This document provides the procedure to be followed to validate the scaleup from a 1,600,000 tablet batch size to a 4,800,000 tablet batch size. The 1,600,000 batch size has been previously validated. It applies to the next three consecutive batches to be produced.

SCOPE:

This protocol is designed to be prospective in nature.

The guidelines presented here include all steps of the manufacturing process which may have an impact on product quality. They are as follows:

Blending
Compression

The process is identical to the 0.25 mg strength which was previously validated. The formula is also the same except for dose related differences. Also the 4,800,000 tablet batch size is made by mixing three batches of 1,600,000 tablet batch size upto lubrication stage which is performed in the large blender. Therefore there is no difference in the larger batch size.

Raw material testing will not be done for this batch size since they have been validated for the smaller batch size.

Details of the process will be found in the completed copies of the Manufacturing Batch Records which are available in the file. A summary of the process is found on the attached flow chart. The major equipment used will be documented and monitored as described in the appropriate section below.

Temperature and humidity will be monitored in the production area on a daily basis.

The data gathered during the course of this study will be evaluated and any adjustments to the predetermined specifications or guidelines will be made as warranted based on the results of the three validation batches.

PROCEDURE:

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
 MPR NO. 14504 REV.00 PROTOCOL NO: 14504-01

BLENDING UNIFORMITY

The first preblend will be produced in the 3 cu.ft. Twin Shell Blender, (#32). The speed will not be monitored since heavier loads have been validated without any observable differences.

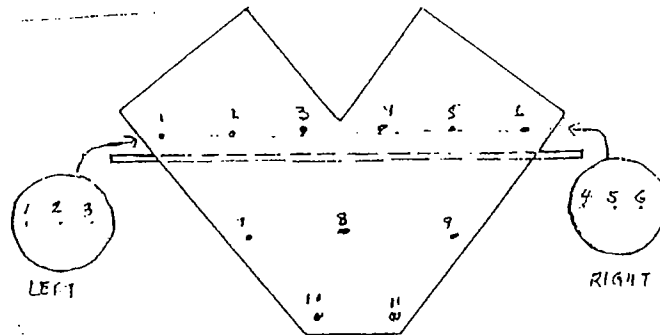
The blend in this step will be subjected to further processing, no sampling will be taken at this point.

The second blend will be produced in the 10 Cu Ft. Twin Shell Blender, (#35). The speed will not be monitored since heavier loads have been validated without any observable differences.

The sampling plan for this blend is designed to evaluate overall blend uniformity, and those points in the blender where uniformity is most difficult to achieve. This is done to assure that complete blending is done since the next step is only lubrication. Samples are to be taken from the points shown below using only the 36 inch (small chamber) single port thief. The sample drawn should be about 305 mg which is three times the single dosage unit, and should be submitted to the laboratory in "Butter Paper."

SAMPLING POINTS

- | | |
|------------------------------|--------------------|
| 1. Left Column - Top left | 7. Middle - Left |
| 2. Left Column - Top Center | 8. Middle - Center |
| 3. Left Column - Top Right | 9. Middle - Right |
| 4. Right Column - Top left | 10. Bottom - Left |
| 5. Right Column - Top Center | 11. Bottom - Right |
| 6. Right Column - Top Right | |



The samples are to be analyzed individually, without being ground, for Digoxin. No composite samples are to be prepared. The sample weight used for analysis should approximate 101.6 mg, which is the amount of this blend which would be present in one unit of the tablet.

Acceptance criteria is 85.0 - 115.0 % Th for the individual data points.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
 MPR NO. 14504 REV.00 PROTOCOL NO: 14504-01

The final blend will be produced in the 50 Cu Ft. Double Cone Blender, Gemco Blender, 23 rpm. (#36). The speed will not be monitored since heavier loads have been validated without any observable differences.

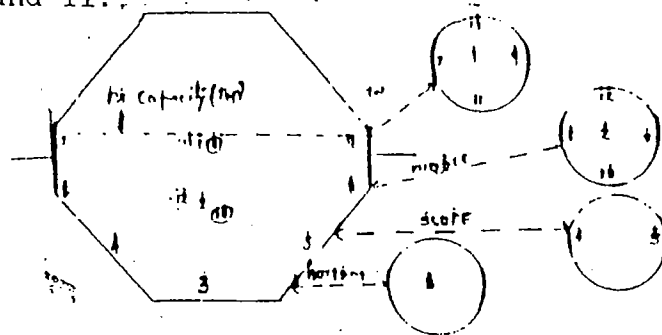
The sampling plan for the final blend is designed to evaluate overall blend uniformity, and those points in the blender where uniformity is most difficult to achieve. Samples about 315 mg are to be taken from the points shown below using only the 72 inch (small chamber) single port thief. This is required to approximate as close as possible to three times the dosage unit.

Three samples of about 150 g will be taken from the top center, middle center and bottom center of the blender. These sample will be tested for physical characterization which includes; bulk and tap density and particle size analysis. This data is for characterization only and these parameters will not be used to monitor routine production. Therefore, acceptance criteria will not be established.

SAMPLING POINTS

- | | |
|--------------------|--------------------|
| 1. CENTER - Top | 8. RIGHT - Middle |
| 2. CENTER - Middle | 9. RIGHT - Top |
| 3. CENTER - Bottom | 10. FRONT - Middle |
| 4. LEFT - Slope | 11. FRONT - Top |
| 5. RIGHT - Slope | 12. REAR - Middle |
| 6. LEFT - Middle | 13. REAR - Top |
| 7. LEFT - Top | |

Note - On the diagram below points 12 and 13 are directly behind 10 and 11.



The samples are to be analyzed individually, without being ground, for Digoxin. No composite samples are to be prepared. The sample weight used for analysis should approximate 105.0 mg, which is the amount of this blend which would be present in one unit of the tablet.

Acceptance criteria is 85.0 - 115.0 % Th for the individual data points.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
 MPR NO. 14504 REV.00 PROTOCOL NO: 14504-01

COMPRESSION

Compression will be accomplished using the stokes 45 station tablet press. The speed will be determined and documented during the validation study.

During compression samples will be collected every hour by QA. These samples will be evaluated for individual tablet weight, thickness, and hardness. This will be 10 tablets for weight, and five each for thickness and hardness. Front and rear samples will be tested separately and will not be composited for any test in this section unless specifically stated.

The hourly samples should be arranged chronologically and the batch divided into thirds. Each third should be evaluated as described below for all tests except content uniformity and dissolution. The samples for each test should be prepared by selecting, as close as possible, an equal number of tablets from each hourly sample. If selecting one tablet per hour results in a greater number of tablets than the test requires the distribution should be as even as possible.

TEST	N
Friability	10 g - 1 Run

Content Uniformity testing is to be run across the entire batch. A 30 tablet sample is to be run for content uniformity from the front and rear separately. The tablets selected for testing should be weighed prior to testing and their identity maintained. The tablets should be selected as evenly distributed as possible throughout the batch.

Dissolution testing is to be run across the entire batch. A 12 tablet sample is to be run for Dissolution from the front and rear separately. The tablets selected for testing should be weighed prior to testing and their identity maintained. The tablets should be distributed as evenly as possible throughout the batch.

The hardness and tablet press speed studies will not be performed for this batch size since the study was performed during the manufacture of 1,600,000 tablet batch size and the same type of press will be used here.

Data analysis will consist of Average and Standard Deviation, with comparison both within and across the three batches. The data collected within each batch will also be evaluated for any possible trends.

AMIDE PHARMACEUTICAL, INC.

PROCESS VALIDATION PROTOCOL - DIGOXIN TABLETS 0.125 mg
MPR NO. 14504 REV.00 PROTOCOL NO: 14504-01

An overall composite sample will be prepared from all of the hourly samples. This data will provide the basis for product release and will also be the initial data for stability.

Acceptance criteria will be as follows:

Target Weight (1 tablet):	105.0 mg
Target Weight (10 tablets):	1.050 g
Weight Range (1 tablet):	0.097 - 0.113 g
Thickness:	2.0 - 3.0 mm
Hardness:	1.0 - 6.0 KP
Friability	NMT 1%
Identification	Meets requirements.
Content Uniformity	85.0% - 115.0% (RSD NMT 6.0%)
Dissolution	Meets USP Requirement.
Assay	90.0 - 105.0%

AMIDE PHARMACEUTICAL, INC.

BATCH FLOW CHART FOR DIGOXIN TABLETS 0.125 mg
BATCH SIZE: 4,800,000 TABLETS
MPR # 14504, REV # 00
PROTOCOL NO: 14504-01

PART 1, 2 AND 3

12.040 kg Corn Starch, NF ----->	Twin Shell, 3Cu.Ft. Blender #32 Blend for 10 min with Intensifier bar ON.
0.200 kg Digoxin, USP ----->	
0.160 kg D&C Yellow #10 Aluminum Lake15-20%>	
6.400 kg Croscarmellose Sodium, NF ----->	

28.56 kg Lactose Hydrous, Impalpable, NF -->	Twin Shell, 3Cu.Ft. Blender #32. Blend for 10 min. with Intensifier Bar ON and blend for 10 min. with intensifier bar OFF
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32.00 kg Starch Pregelatinized, NF ----->	Twin Shell, 10Cu.Ft. Blender #35 Blend for 10 min. with intensifier bar OFF
32.00 kg Microcrystalline Cellulose NF(101)>	

51.20 kg Lactose Anhydrous, NF (DT) ----->	Twin Shell, 10Cu.Ft. Blender #35, Blend for 10 min. with Intensifier Bar ON and blend for 10 min. with intensifier bar OFF
(QA Blend Samples)	

FINAL BLEND

14.40 kg Stearic Acid, NF ----->	Gemco, 50 Cu. Ft. Blender #36 Blend for 5 min.
1.920 kg Silicon Dioxide, NF ----->	
Part 1, 2 and 3----->	

(QA Final Blend Samples)

Compress Tablets ----->	Tablet Press Stokes 45 station
(QA Samples - Every hour)	

AMIDE PHARMACEUTICAL, INC.

BATCH FLOW CHART FOR DIGOXIN TABLETS 0.125 mg
BATCH SIZE: 4,800,000 TABLETS
MPR # 14504, REV # 00
PROTOCOL NO: 14504-01

PART 1, 2 AND 3

12.040 kg Corn Starch, NF ----->	Twin Shell, 3Cu.Ft. Blender #32 Blend for 10 min with Intensifier bar ON.
0.200 kg Digoxin, USP ----->	
0.160 kg D&C Yellow #10 Aluminum Lake15-20%>	
6.400 kg Croscarmellose Sodium, NF ----->	

28.56 kg Lactose Hydrous, Impalpable, NF -->	Twin Shell, 3Cu.Ft. Blender #32. Blend for 10 min. with Intensifier Bar ON and blend for 10 min. with intensifier bar OFF
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32.00 kg Starch Pregelatinized, NF ----->	Twin Shell, 10Cu.Ft. Blender #35 Blend for 10 min. with intensifier bar OFF
32.00 kg Microcrystalline Cellulose NF(101)>	

51.20 kg Lactose Anhydrous, NF (DT) ----->	Twin Shell, 10Cu.Ft. Blender #35, Blend for 10 min. with Intensifier Bar ON and blend for 10 min. with intensifier bar OFF
(QA Blend Samples)	

FINAL BLEND

14.40 kg Stearic Acid, NF ----->	Gemco, 50 Cu. Ft. Blender #36 Blend for 5 min.
1.920 kg Silicon Dioxide, NF ----->	
Part 1, 2 and 3----->	

(QA Final Blend Samples)

Compress Tablets ----->	Tablet Press Stokes 45 station
(QA Samples - Every hour)	